Supreme Court, U.S.
FILED

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No. 03 557 OCT 10 2003

IN THE

Supreme Court of the United States

ST. LOUIS UNIVERSITY, a corporation,

Petitioner,

—v.—

AMERICAN CYANAMID COMPANY,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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77 pp

QUESTION PRESENTED

1. In light of *Berkovitz v. United States*, 486 U.S. 531 (1988), and the decisions of the Third, Fourth, Eighth, and Ninth Circuits, is it sufficient to hold a manufacturer liable for oral polio vaccine ("OPV") injuries upon a showing that (1) the federal safety regulations were violated, (2) the non-compliant vaccine caused the disease, and (3) but for the release and marketing of the non-compliant vaccine no OPV injury was possible?

PARTIES IN THE PROCEEDING BELOW

1. St. Louis University ("SLU"), a corporation, Petitioner;

2. American Cyanamid Company ("Cyanamid"), a corporation;

3. United States Government.*

CORPORATE DISCLOSURE STATEMENT

St. Louis University makes this corporate disclosure statement pursuant to Supreme Court Rule 29.6:

1. St. Louis University has no parent corporation.

2. No publicly-held corporation owns 10 percent or more of the stock of St. Louis University.

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* Although the Fourth Circuit decision giving rise to this Petition did not involve the Government as a party, the Government was involved in the District Court proceeding out of which the Fourth Circuit decision arose. *See* CITATIONS OF OPINION AND ORDERS IN CASE, *infra*.

TABLE OF CONTENTS

	PAGE
TABLE OF AUTHORITIES	v
CITATIONS OF OPINIONS AND ORDERS IN CASE	1
JURISDICTIONAL STATEMENT	2
FEDERAL REGULATIONS INVOLVED	2
STATEMENT OF THE CASE	2
SUMMARY OF FACTS	4
THE DISTRICT COURT DECISION	5
THE FOURTH CIRCUIT APPELLATE DECISIONS	8
EXISTENCE OF JURISDICTION IN COURTS BELOW	11
ARGUMENT FOR ALLOWANCE OF THE WRIT	12
I. In A Radical Departure From Traditional Federal Practice That Warrants Correction By The Supreme Court, The Fourth Circuit Disregarded The Binding United States Supreme Court Precedent Of *Berkovitz* That Subjected a Product Approver To Liability For Violating Federal OPV Safety Regulations.	13

PAGE

II. In A Radical Departure From Traditional Federal Practice That Warrants Correction By The Supreme Court, The Fourth Circuit Panel Disregarded The Binding Fourth Circuit Precedent Of *Sabin IV* That Subjected a Product-Approver to Liability For Violating Federal OPV Safety Regulations 15

III. The Fourth Circuit's Decision Shielding Cyanamid From Liability Conflicts With Third, Eighth, and Ninth Circuit Precedent Subjecting a Product Approver To Liability For Violating Federal OPV Safety Regulations, And Thereby Destroys Uniformity In The Federal OPV Regulations 17

CONCLUSION 20

APPENDIX

A. *American Cyanamid Company v. St. Louis University*, 336 F.3d 307 (4th Cir.2003) 1a

B. *United States v. St. Louis University*, 336 F.3d 294 (4th Cir.2003) 9a

C. *St. Louis University v. United States*, 182 F. Supp. 2d 494 (D. Md. 2002) 34a

TABLE OF AUTHORITIES

Federal Cases PAGE

American Cyanamid Company v. St. Louis University, 336 F.3d 307 (4th Cir. 2003).....1, 3, 4, 5, 8, 9, 12, 15, 16

Baker v. United States, 817 F.2d 560 (9th Cir. 1987) 12, 18

Berkovitz v. United States, 486 U.S. 531 (1988) .....i, 8, 12, 13, 14, 19

Griffin v. United States, 500 F.2d 1059 (3rd Cir. 1974) 12, 17

Loge v. United States, 662 F.2d 1268 (8th Cir. 1981) 12, 18

In re Sabin Oral Polio Vaccine Product Liability Litigation, 763 F. Supp. 811 (D. Md.1991) *aff'd*, 984 F.2d 124 (4th Cir. 1993).....vi, 6, 7

In re Sabin Oral Polio Vaccine Product Liability Litigation, 774 F.Supp. 952 (D. Md. 1991) *aff'd*, 984 F.2d 124 (4th Cir. 1993)..... 6

In re Sabin Oral Polio Vaccine Product Liability Litigation, 984 F.2d 124 (4th Cir. 1993)..... 11, 15

St. Louis University v. United States, 182 F. Supp.2d 494 (D. Md. 2002).....1, 4, 5, 6, 7, 10, 14, 16

PAGE

United States v. St. Louis University,
336 F.3d 294 (4th Cir. 2003) ... 1, 4, 5, 8, 9, 12, 16

State Cases

Todd v. Watson, 501 S.W.2d 48 (Mo. 1973) 16

Robinson v. Missouri State Highway & Transp. Comm'n, 24 S.W.3d 67 (Mo. Ct. App. 2000) (per curiam) 17

Statutes

28 U.S.C. § 1254(1) 2

28 U.S.C. § 1292(b) 12

28 U.S.C. §§ 1331, 1332 11

Regulations

42 C.F.R. § 73.110 *et seq.*,* *renumbered* at 21 C.F.R. § 630.10, *et seq.* ..... vi, 2

Miscellaneous

Restatement (Second) of Torts § 431 16

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* To be consistent with the citation of these federal regulations by the District Court below ever since it presided over the multi-district *Sabin* OPVcases, Petitioner will cite to these OPV regulations by their original number, even though they were later renumbered in 21 C.F.R. §§ 630.10-630.17. *See In re Sabin Oral Polio Vaccine Products Liability Litigation*, 763 F. Supp. 811, 813 n.2 (D. Md. 1991) ("*Sabin II*") ("I will cite to them (as I did in my earlier opinion) by their original number").

CITATIONS OF OPINIONS AND ORDERS IN CASE

The decision giving rise to this Petition was issued by the United States Court of Appeals for the Fourth Circuit: *American Cyanamid Company v. St. Louis University*, 336 F.3d 307 (4th Cir. 2003). The opinion is attached as Appendix A. (A companion decision, *United States v. St. Louis University*, 336 F.3d 294 (4th Cir. 2003), was also issued by the Fourth Circuit, and is attached as Appendix B for the Court's convenience.[1])

The United States District Court for the District of Maryland was the trial court in this matter, and addressed in a single opinion the claims of St. Louis University against both Cyanamid, the vaccine manufacturer, and the United States Government, which tested and approved the vaccine. Upon appeal, the Fourth Circuit split the matter apart and issued the two individual decisions cited above. It affirmed the District Court's grant of summary judgment in favor of American Cyanamid against SLU, and it reversed the District Court's grant of summary judgment in favor of SLU against the Government, remanding for entry of judgment in favor of the Government.

The District Court opinion and order that gave rise to both appellate decisions, *St. Louis University v. United States*, 182 F. Supp. 2d 494 (D. Md. 2002), is attached as Appendix C.

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[1] Petitioner is submitting a separate Petition for Certiorari regarding *United States v. St. Louis University*, 336 F.3d 294 (4th Cir. 2003). At the appellate level, SLU petitioned for rehearing *en banc* in that matter, a petition denied by the Fourth Circuit on Aug. 12, 2003. Accordingly, that Petition for Certiorari, which involves the distinct issue of Government liability, will be submitted to this Court within 90 days of August 12, 2003.

JURISDICTIONAL STATEMENT

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1). The Fourth Circuit's judgment was entered July 16, 2003. The instant Petition is filed with 90 days of that decision, pursuant to Supreme Court Rule 13.

FEDERAL REGULATIONS INVOLVED

This case involves a contribution claim made by St. Louis University against the US Government and American Cyanamid. SLU was sued by Danny Callahan for administering to him a defective vaccine, a vaccine that gave him polio. Callahan was awarded $16 million in his suit. Because the vaccine was negligently manufactured and distributed by American Cyanamid, SLU sought contribution from Cyanamid.

The regulations at issue specify the mandatory safety requirements that govern the manufacture and sale of polio vaccines. Cyanamid violated all of the safety regulations, 42 C.F.R. § 73.110 *et seq.*, in its manufacture and sale of its Orimune oral polio vaccine ("OPV").[2]

STATEMENT OF THE CASE

The Supreme Court should grant certiorari to resolve an issue which will promote the integrity of the federal

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[2] Petitioner had difficulty converting a copy of the 42 C.F.R. § 73.110 *et seq.* original regulations (which are from 1961) into a legible 6 by 9 inch typographic format and thus could not include them in the Petition Appendix. Accordingly, should the Court request a copy of those regulations, Petitioner will file an 8.5 by 11 inch copy with the Court. If that is insufficient, Petitioner will of course do whatever the Court otherwise directs.

regulatory process and promote uniformity of decisions among the Circuit courts.

The Fourth Circuit's decision has undermined the effective reach and purpose of the federal OPV regulations whose express purpose was to insure safe vaccines for all Americans. The Fourth Circuit interpreted Missouri law as holding plaintiff to a causation standard which insulates manufacturers from liability and negates the force and purpose of the federal vaccine regulations. Second, the Fourth Circuit's decision is in conflict with its previous decisions and those of other Circuits, which analyzed virtually identical facts under identical tort regimes with respect to the same regulatory framework.

The gravamen of the case is as follows. Cyanamid manufactured a polio vaccine that violated federal safety regulations in that it was excessively neurovirulent. The manufacturers also represented that the vaccine did in fact meet the regulations when it knew those claims were false. The Fourth Circuit's decision granting Cyanamid summary judgment requires that, to establish liability, petitioner must prove that the OPV victim would not have contracted polio from a compliant vaccine. That is an impossible liability requirement. Petitioner has proved excessive neurovirulence was the cause of the injury.

The Fourth Circuit's proximate cause analysis destroys the purpose of the safety regulations. It concluded that "SLU has simply failed to present any competent evidence showing that the defect in the vaccine—excessive neurovirulence—proximately caused SLU's injuries." *Cyanamid*, 336 F.3d at 310. The Fourth Circuit's reasoning was that were the regulations followed, Danny might have gotten polio anyway, owing to the inherent risk of polio even compliant live vaccines pose. *Id.* In short, because plaintiff did not prove Danny got polio

because of the *additional* risk posed to him by a non-compliant vaccine, the Fourth Circuit held that SLU did not satisfy causation.

First, there is no evidence that any live polio vaccine would have been able to satisfy the regulations during the applicable time period. Accordingly, had the regulations been followed, the only vaccine available to Danny would have been the inactive Salk vaccine, which presents *no polio risk*. As a matter of logic, the evidence presented by plaintiff—that the live vaccine was excessively neurovirulent and that its label not only failed to warn doctors that the vaccine was not in compliance with the applicable regulations, but falsely claimed compliance—proves proximate cause. No doctor would prescribe to his patient an excessively neurovirulent live vaccine that did not meet government regulations when a perfectly safe inactive vaccine was available.

Moreover, even assuming that some compliant version of a live polio vaccine could have made it to market, no proximate cause standard could require that Danny prove he got polio because of the *additional* risk. That is an impossible standard to meet. Contrary to the Fourth Circuit's view, neither Missouri nor any state's law defeats the claim.

The Court should grant certiorari.

SUMMARY OF FACTS

SLU paid a $ 16 million Missouri state-court judgment to the family of Danny Callahan, who contracted paralytic poliomyelitis after ingesting the Orimune polio vaccine. *St. Louis University v. United States*, 182 F. Supp.2d, 496-98 (D. Md. 2002); *United States v. St. Louis University*, 336 F.3d 294 (4th Cir. 2003); *American Cyanamid v. St. Louis University*, 336 F.3d 307 (4th Cir. 2003). Approximately one month after receiving the

dose of Orimune, Danny developed a fever and perirectal abscesses. *St. Louis University v. United States*, 182 F. Supp.2d at 496-98. He was treated at Cardinal Glennon Hospital by SLU employees. *Id.* That judgment paid by SLU arose from SLU employee's actions in treating 3-month old Danny Callahan. *Id.* Although the abscesses improved, Danny's legs and left arm were permanently paralyzed. *Id.* The polio virus was isolated in Danny's stool, and doctors (and the District Court) concluded that Danny contracted paralytic poliomyelitis from the Orimune vaccine of live polio Type III. *Id:*

SLU subsequently asserted Cyanamid proximately caused Danny's paralytic poliomyelitis by manufacturing and marketing the excessively neurovirulent Orimune polio vaccine in violation of the applicable OPV neurovirulence regulations. *Cyanamid*, 336 F.3d. at 309. SLU also asserted the Government proximately caused Danny's polio by improperly approving and licensing the vaccine in violation of the applicable regulations. *United States v. St. Louis University*, 336 F.3d at 298.

THE DISTRICT COURT DECISION

The District Court opinion, *St. Louis University v. United States*, 182 F. Supp.2d 494 (D. Md. 2002), adjudicated both SLU's claims against the Government and against Cyanamid. To be properly understood the District Court's analysis of the claims against Cyanamid should be evaluated in contrast to its analysis of the claims against the Government. Accordingly, a brief review of the District Court's Government analysis follows.

Judge Frederick Motz of the District Court found that by releasing the Orimune vaccine lots the "United States is liable in contribution because its violations of its own regulations constituted negligence and were a proximate

cause of Callahan's paralysis." *St. Louis University v. United States*, 182 F. Supp.2d at 500. In making that determination, the District Court concluded "if the government had not wrongfully approved the seed from which the vaccine was derived, Callahan would never have been administered a dose of Orimune and would never had contracted polio" because the excessively neurovirulent vaccine given to Danny would never have been released at all. *Id.* at 499. The District Court further explained that "the neurovirulence criteria of the OPV regulations—which the government itself had adopted—provided the 'best available scientific standard' for determining excessive neurovirulence and that the government had therefore increased the risk of harm to the public." *Id.* at 502 (citing *In re Sabin Oral Polio Vaccine Prod. Liab. Litig.*, 774 F.Supp. 952 (D. Md. 1991) ("*Sabin III*") at 955). This was an echo of the District Court's conclusions in *Sabin III*, where Judge Motz found that because "neurovirulence test results exceeded the regulatory criteria, [the Government] increased the risk of harm to persons who were vaccinated. . .". *Sabin III*, 774 F.Supp. at 955.

After holding the Government liable, the District Court, in what it admitted was a seemingly "asymmetrical, paradoxical, or even perverse" holding, absolved Cyanamid from liability. *St. Louis University v. United States*, 182 F. Supp.2d at 500. This is especially puzzling because the District Court had before it not only the testimony of the regulators from the *In Re Sabin Oral Polio Vaccine Prod. Liab. Litig.*, 763 F.Supp 811 (D. Md. 1991) ("*Sabin II*") case, it had American Cyanamid's own documents which detailed the entire history of these violations and were authored by the key principals of the company during the period of 1962 through the 1980s. The upshot of the documents is that Cyanamid knew it was violating the regulations but, nevertheless, decided to turn a blind eye to

these results. "A final meeting was held December 21. According to a Lederle memorandum, all the participants agreed 'that [Lederle's] type 3 is more neurovirulent than type 1 reference.' " *Sabin II*, 763 F.Supp. at 820-821.[3]

The basis of the District Court's decision to absolve Cyanamid was Judge Motz's erroneous conclusion that the causation standard that applied to Cyanamid was somehow different than one that applied to the Government:

> [I]n analyzing the element of proximate cause in claims against Cyanamid, the focus must be on whether the plaintiff can prove that it was a defect in the OPV that resulted in his injury, not simply—as in a case against the Government—whether he had been exposed to OPV derived from a seed that had been improperly approved in violation of the regulatory process.

St. Louis University v. United States, 182 F. Supp.2d at 500.

Thereby, the District Court contradictorily concluded —in contrast to remarks it made about Orimune in the Government context—that with respect to the Cyanamid causation inquiry Orimune was not "excessively neurovirulent when administered to humans or that an OPV meeting the regulatory criteria would not have equally caused the Sabin III plaintiffs to contract polio." *Id.* at 502.

In so concluding, the District Court produced a surreal decision: one where, on the same facts, improperly approving the licensing of OPV caused Danny's triplegia, but improperly manufacturing the same OPV and asking for approval for licensing did not.

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[3] Lederle is a division of American Cyanamid.

THE FOURTH CIRCUIT APPELLATE DECISIONS

The District Court decision, holding the Government liable and absolving Cyanamid, was appealed, respectively, by the Government and by SLU. After entertaining those appeals, the Fourth Circuit issued two separate decisions, one involving Cyanamid, *American Cyanamid Company v. St. Louis University*, 336 F.3d 307 (4th Cir. 2003) and one involving the Government, *United States v. St. Louis University*, 336 F.3d 294 (4th Cir. 2003). Because the Government decision was referred to by the Fourth Circuit in the Cyanamid opinion, the latter is summarized here for the Court's convenience. In sum, the Fourth Circuit's Government decision overturned the District Court finding of liability against the Government, notwithstanding the factual findings that (1) the Government released the excessively neurovirulent Orimune vaccine in violation of the mandatory federal OPV neurovirulence regulations;[4] (2) this excessively neurovirulent Orimune vaccine was received by three-month old Danny Callahan;[5] (3) this Orimune vaccine whose excessive "ability to cause paralytic poliomyelitis"[6] violated the OPV regulations did in fact cause

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[4] *United States v. St. Louis University,* 336 F.3d at 298 (accepting district court's finding that "the vaccine seeds from which the [Orimune] lots were derived did not meet the neurovirulence standards set forth in the governing regulations").

[5] *United States v. St. Louis University,* 336 F.3d at 298 ("The Orimune vaccine received by Danny Callahan was derived from one of the vaccine seeds that the district court in the *Sabin* cases concluded were improperly approved by the government.").

[6] *Berkovitz v. United States*, 486 U.S. 531, 544 n.9 (1988) (Supreme Court defining "neurovirulence")

paralytic poliomyelitis in Danny;[7] and (4) had the Government not violated its own federal OPV regulations, the excessively neurovirulent Orimune vaccine which Danny received would never have been released at all.[8]

The Fourth Circuit's reasoning was the "proximate cause" had not been established against the Government: "we conclude that SLU was required to establish that Danny likely would not have contracted polio . . . from a vaccine that satisfied the government's neurovirulence standards." *United States v. St. Louis University,* 336 F.3d at 302.

In the companion Cyanamid appellate decision, the Fourth Circuit affirmed the District Court's grant of summary judgment, using identical proximate cause reasoning as in the Government appeal: "SLU presented no expert testimony showing that Danny Callahan would not have contracted polio . . . had he been given a vaccine complying with the regulations." *Cyanamid*, 336 F.3d at 309.

There are two obvious problems with the above "proximate cause" reasoning. First—just as the District Court concluded with respect to the Government's improper approval of the product—had Cyanamid actually complied with the regulations, Orimune would never have

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[7] *United States v. St. Louis University,* 336 F.3d at 297 ("doctors ultimately concluded that Danny suffered from vaccine-associated polio").

[8] *United States v. St. Louis University,* 336 F.3d at 298 (accepting district court's finding that Government "violat[ed] its own regulatory standards [by] approving for release vaccine derived from seeds that exceeded the neurovirulence standards"); *see also, id.* at 306 (Luttig, J., dissenting)(explaining that had the Government complied with the OPV regulations, "none of the offending vaccine would have been distributed at all").

reached Danny's lips. It was simply impossible for the defective vaccine to have been manufactured and distributed if the regulations were complied with. Thus, were the regulations followed, Danny would have been inoculated with an alternative vaccine: the Salk vaccine. Importantly, the Salk vaccine cannot cause polio; it is 100% safe. Put another way, if either the Government or Cyanamid had followed the regulations, Danny could not have gotten polio.

Second, the proximate cause standard adopted by the Fourth Circuit requires a showing that, in the words of the District Court, is logically "unknowable and unprovable." *St. Louis University v. United States*, 182 F. Supp.2d at 502 ("Whether or not an oral polio vaccine that complied with the OPV regulations would have caused Callahan and the plaintiffs in the other Sabin cases to contract polio ultimately is unknowable and unprovable"). Namely, the Fourth Circuit required plaintiff to show that Danny would *not* have gotten polio had he taken a hypothetically compliant live vaccine. Of course, since even a hypothetically compliant live vaccine (unlike the Salk vaccine) has an inherent risk of polio, the Fourth Circuit well knew that there could never be such evidence to prove its invented standard. The Fourth Circuit's causation burden is akin to requiring one cheated by a loaded die to prove that a fair die couldn't have also resulted in a losing outcome. That is asking the impossible.

By forcing that impossible proximate cause standard on plaintiff, the Fourth Circuit deliberately ensured that the manufacturer will always escape liability for violating the mandatory federal safety regulations which are enacted to protect the innocent children who are required to be immunized for their good and the public good. Accordingly, the decision conflicts with the precedent of

the Supreme Court, Third Circuit, Fourth Circuit (in the previously decided *In Re Sabin Oral Polio Vaccine Prod. Liab. Litig.*, 984 F.2d 124 (4th Cir. 1993) ("*Sabin IV*"), Eighth Circuit, and Ninth Circuit, which all subjected a product approver, the Government, to liability for releasing non-complaint vaccine in violation of mandatory federal OPV regulations. The fact that the cases referred to herein involve the Government in a product approver capacity rather than a manufacturer does not eliminate the existence of conflict. Rather, it makes the conflict more stark: other Circuits subjected the *product approver* (the government) to liability for a defective vaccine Only by fabricating an impossible causation standard could the Fourth Circuit absolve the actual *product manufacturer*—a party much closer to the victim in the chain of liability—of liability for the same defective vaccine. It is simply unjust that a tortfeasor who fails to obey a single regulatory command, who failed to perform the tests properly, and who failed to submit the data to the Government would escape liability.

This Court should now grant certiorari to resolve this conflict.

EXISTENCE OF JURISDICTION IN COURTS BELOW

This contribution action was commenced in the United States District Court for the District of Maryland. The District Court had jurisdiction over the matter pursuant to the 28 U.S.C. §1331 and 1332.

The District Court granted summary judgment against the Government and in favor of Cyanamid on January 25, 2002. *St. Louis University v. United States*, 182 F. Supp.2d 494 (D. Md. 2002). The District Court certified the order as appropriate for immediate review, and the United States

Court of Appeals for the Fourth Circuit granted the Government and SLU permission to bring interlocutory appeal under 28 U.S.C. § 1292(b). On July 16, 2003, the Fourth Circuit affirmed the District Court's grant of summary judgment in favor of Cyanamid. *American Cyanamid Company v. St. Louis University*, 336 F.3d 307 (4th Cir. 2003).[9]

ARGUMENT FOR ALLOWANCE OF THE WRIT

By rejecting the binding precedent of the Supreme Court in *Berkovitz v. United States*, 486 U.S. 531 (1988) and the Fourth Circuit in *Sabin IV,* and thereby disregarding the fundamental doctrine of *stare decisis*, the Fourth Circuit has radically departed from traditional federal practice. *See* Sup. Ct. R. 10(a) (review on certiorari warranted where decision "so far departed from the accepted and usual course of judicial proceeding . . . as to call for an exercise of this Court's supervisory power").

Moreover, by shielding Cyanamid from liability for violating federal vaccine regulations in manufacturing and marketing a noncompliant vaccine, the Fourth Circuit decision below necessarily conflicts with the logical extension of precedents of the Third,[10] Eighth[11] and Ninth Circuits,[12] all of which subjected a mere product-approver to liability for violating analogous mandatory federal regulations. By force of logic and common-

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[9] The same day, the Fourth Circuit reversed the District Court's grant of partial summary judgment in favor of SLU, and directed entry of final judgment in favor of the Government. *United States v. St. Louis University,* 336 F.3d 294 (4th Cir. 2003).

[10] *Griffin v. United States*, 500 F.2d 1059 (3rd Cir. 1974).

[11] *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981).

[12] *Baker v. United States*, 817 F.2d 560 (9th Cir. 1987).

sense, if those merely approving the product are subject to liability, the same must also be true of those manufacturing the product. Thus the conflict presents itself: where in several circuits those approving the product are subject to liability, in the Fourth Circuit the party *actually manufacturing* the product is shielded. *See* Sup. Ct. R. 10(a) (review on certiorari warranted where "a United States court of appeals has entered a decision in conflict with the decision of another United States court of appeals on the same important matter"). That simply cannot be right.

This Court should now grant certiorari to review and reverse the Fourth Circuit decision. By holding Cyanamid, the defective product manufacturer, liable for violating mandatory federal vaccine safety regulations, the Supreme Court would restore uniformity to the federal vaccine regulations and uphold public confidence in the regulatory system and the rule of law itself.

I. In A Radical Departure From Traditional Federal Practice That Warrants Correction By The Supreme Court, The Fourth Circuit Disregarded The Binding United States Supreme Court Precedent Of *Berkovitz* That Subjected a Product Approver To Liability For Violating Federal OPV Safety Regulations.

In *Berkovitz v. United States*, 486 U.S. 531 (1988), the Government was sued under the FTCA for releasing the excessively neurovirulent Orimune vaccine in violation of the federal OPV safety regulations. The Government sought to escape liability under the FTCA's discretionary function exception. The *Berkovitz* Court rejected the discretionary function doctrine as inapplicable, paving the way for a product-approver to be subject to liability. In so doing, the Court noted the heightened duty product manufacturers bore, above and beyond the duty of the

Government: "[the] regulations place[ ] an obligation on manufacturers to examine all vaccine lots prior to distribution to ensure that they comply with regulatory standards. . . . These regulations, however, do not impose a corresponding duty" on the Government. *Berkovitz*, 486 U.S. at 545-546. The implication of *Berkovitz* was clear: if the Government, the party with the *lesser* obligation, is subject to liability for violating the regulations, then so too must be the manufacturer.

In the instant case, Cyanamid violated the federal OPV regulations by producing and distributing the noncompliant vaccine that paralyzed Danny. Importantly, violating the regulations has a clear physical consequence: it "increased the risk that several more individuals would contract polio as a result of exposure to OPV than would have done if the OPV regulations had been strictly followed." *St. Louis University v. United States*, 182 F. Supp.2d at 503. The fact that such remarks were made in the context of the Government violating regulations does not undo their force: Cyanamid's violations in manufacturing the vaccine increased the risk of contracting polio just as much as did the Government's violations in approving the vaccine.

By shielding Cyanamid from liability in case wherein Cyanamid exposed product users to a defective product that increased the risk of polio, the Fourth Circuit has rejected binding Supreme Court *Berkovitz* precedent that subjects product-approvers, and by necessary extension product manufacturers, to liability for violating OPV safety regulations that prohibit the distribution of an excessively neurovirulent vaccine. Accordingly, this Court should now grant certiorari to correct the Fourth Circuit for "so depart[ing] from the accepted and usual course of judicial proceedings" in rendering the below decision in disregard of binding Supreme Court prece-

dent, *stare decisis*, and the proper order of our federal judicial system. Sup. Ct. R. 10(a).

II. In A Radical Departure From Traditional Federal Practice That Warrants Correction By The Supreme Court, The Fourth Circuit Panel Disregarded The Binding Fourth Circuit Precedent Of *Sabin IV* That Subjected a Product-Approver to Liability For Violating Federal OPV Safety Regulations.

In addition to improperly rejecting the binding Supreme Court precedent of *Berkovitz*, the Fourth Circuit flouts the fundamental doctrine of *stare decisis* by rejecting the binding Fourth Circuit precedent of *Sabin IV*. *See Sabin IV*, 984 F.2d at 128 (4th Cir. 1993) (holding product *approver* did proximately cause and was liable for plaintiffs' paralytic poliomyelitis by releasing Orimune in violation of mandatory federal neurovirulence regulations); *compare American Cyanamid Company v. St. Louis University*, 336 F.3d 307 (4th Cir. 2003) (holding product *manufacturer* did *not* proximately cause and was not liable for plaintiff's paralytic poliomyelitis by releasing Orimune in violation of mandatory federal neurovirulence regulations).

Sabin IV explicitly held that the causal connection between plaintiff's injuries and violation of the OPV regulations was "logical, sensible and direct." *Sabin IV*, 984 F.2d at 128 (affirming district court's conclusion of same). The fact that *Sabin IV* involved the Government's violations, and not Cyanamid's, does not mean the its reasoning is not binding. Causation is causation. Specifically, proximate cause is the same whether applied to a product approver or a product manufacturer, a truism the Fourth Circuit panel admitted, explaining that the approver/manufacturer distinction "has no effect on the general

rules of causation." *United States v. St. Louis University*, 336 F.3d at 302. Thus the below decision had no legal or factual basis on which to reach the conclusion it reaches, other than it is unhappy with the reasoning *Sabin IV*.[13]

However, in a transparent effort to ignore binding proximate cause reasoning issued under an identical tort regime in *Sabin IV*, the Fourth Circuit panel seized upon an imaginary distinction. It claimed Missouri law to be different than the Florida and Maryland law governing *Sabin IV*, which amounted to a sophisticated excuse from having to follow the precedent in *Sabin IV*. Yet in its vigor to demonstrate this alleged difference, the panel contorted Missouri proximate cause law into absurdity. It demanded of SLU a showing that "Danny Callahan would not have contracted polio or would have contracted a less severe case had he been given a vaccine complying with the regulations." *Cyanamid*, 336 F.3d at 310. Of course, Missouri law requires no such impossible proof of causation. Nor does the law of any state. All that is required, as in *Sabin IV*, is that the defect was a substantial factor in bringing about a reasonably related harm.[14]

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[13] Petitioner is not suggesting the Fourth Circuit can never reverse course. However, because the below proceeding occurred before a *panel*, the panel does not have the authority to ignore or overturn binding precedent. Only the Fourth Circuit *en banc*, or this Court, can do that. *See St. Louis University v. United States*, 336 F.3d at 305 (panel "is bound to abide . . . until [the Fourth Circuit] *en banc* or the Supreme Court holds otherwise") (Luttig, J., dissenting). To do otherwise is to violate *stare decisis*.

[14] Missouri law adopts the standard of Restatement (Second) of Torts § 431 (conduct is proximate cause of injury if it "is a substantial factor in bringing about the harm"). S*ee Todd v. Watson*, 501 S.W.2d 48, 52 (Mo. 1973) (citing Rest. (2d) Torts § 431: "To be a legal cause of harm to another, one's conduct must be a substantial factor in brining about the harm"); *see also Robinson v. Missouri State*

Thereby, by flouting the fundamental principle of *stare decisis* in its rejection of the binding principle of *Sabin IV*, the Fourth Circuit panel "so far departed from the accepted and usual course of judicial proceedings" as to warrant review and reversal by the Supreme Court on certiorari. Sup. Ct. R. 10(a).

III. The Fourth Circuit's Decision Shielding Cyanamid From Liability Conflicts With Third, Eighth, and Ninth Circuit Precedent Subjecting a Product Approver To Liability For Violating Federal OPV Safety Regulations, And Thereby Destroys Uniformity In The Federal OPV Regulations.

The decisions of sister Circuits illuminate the Fourth Circuit's radical and unwarranted break from the liability scheme the federal OPV regulations contemplate.

The Third Circuit, in *Griffin v. United States*, 500 F.2d 1059 (3rd Cir. 1974), affirmed a finding of liability against the Government and held that the proximate cause standard against a product approver was satisfied under conditions functionally identical to the instant case. In analyzing the issue of causation, the Third Circuit affirmed the district court's finding of proximate cause, concluding that proximate cause was satisfied because (a) plaintiff developed Type III polio from a vaccine, as did Danny, and that (b) plaintiff ingested a

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Highway & Transp. Comm'n, 24 S.W.3d 67, 78 (Mo. Ct. App. 2000) (per curiam) (proximate cause test is whether "the injury appears to be the reasonable and probable consequence of the act or omission of the defendant . . . . It is only necessary that the party charged knew or should have known there was an appreciable chance some injury would result") (internal citations omitted). Here, by manufacturing the excessively neurovirulent vaccine in violation of the regulations and falsely claiming compliance with same, Cyanamid created an appreciable chance that one exposed to the defective vaccine would contract polio.

noncompliant vaccine, as did Danny. *Griffin,* F.2d 1059 at 1070.

The Eighth Circuit in *Loge v. United* States, 662 F.2d 1268 (8th Cir. 1981), held the FTCA discretionary function exception did not shield the Government for violating the mandatory federal OPV regulations. *Id.* at 1272-74. The Court further explained that:

> [T]he Government increased the risk of harm to the Loges by licensing an allegedly untested product, Orimune, and by releasing to the public an allegedly untested or negligently tested lot of that vaccine: if either the product itself or a particular lot of that product failed to conform to the standards established by the regulations, then proper testing or proof of testing would have revealed the nonconformity and the vaccine would never have been disseminated to Todd Loge.

Loge, 662 F.2d at 1274. Accordingly, the Eighth Circuit deemed a product approver subject to liability wherein it (a) violated applicable regulations and (b) increased the risk of harm to those taking the vaccine. *Id.* at 1274-1275. Both are true of the product manufacturer here.

The Ninth Circuit, in *Baker v. United* States, 817 F. 2d 560 (9th Cir. 1987), held that product approvers could not violate mandatory OPV safety regulations "that serve to protect susceptible persons from contracting the [polio] disease." *Id.* at 561. Ultimately, *Baker* concluded that the product approver "may be subjected to tort liability for the alleged negligence of an agency employee in failing to follow a specific mandatory [OPV] regulation." *Id.* at 563-65. It specifically noted that "[a]gency employees charged with enforcing poliovirus vaccine safety standards must require the submission of the test data." *Id.* at 566. Clearly the Eighth Circuit does not

believe that the manufacturer, who submits said data, is to be shielded from liability.

In vivid contrast to the foregoing decisions, the Fourth Circuit categorically absolved a product manufacturer from liability, imposing an unprovable proximate cause standard. The Fourth Circuit did so even though Cyanamid manufactured and marketed a product that failed to comply to the applicable regulations—regulations which the Supreme Court explained were more onerous than the safety regulations binding the Government. *Berkovitz*, 486 U.S. at 545-546. Therefore, the below Fourth Circuit decision to shield a product manufacturer from liability for violating regulations governing the manufacture and release of the Orimune vaccine conflicts with Third, Eighth, and Ninth Circuit decisions that refused to shield a product approver from liability for violating regulations governing the manufacture and release of the Orimune vaccine. Accordingly, this Court should now grant certiorari to resolve this conflict. *See* Sup. Ct. R. 10(a), *supra.*

CONCLUSION

For the reasons set forth above, this Petition for Writ of Certiorari should be granted.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOURTH CIRCUIT

No. 02-1235

Argued: January 22, 2003
Decided: July 16, 2003

AMERICAN CYANAMID COMPANY,

Plaintiff-Appellee,

—v.—

ST. LOUIS UNIVERSITY,

Defendant-Appellant.

ARGUED: Marc Simon Moller, Kreindler & Kreindler, New York, New York, *for Appellant*. David Patrick Donovan, Wilmer, Cutler & Pickering, McLean, Virginia, *for Appellee*. ON BRIEF: Mark R. Dunn, Herzog, Crebs & McGhee, L.L.P., St. Louis, Missouri; Stanley P. Kops, Bala Cynwyd, Pennsylvania; Rex Carr, Carr, Korein, Tillery, Kunin, Montroy & Glass, East St. Louis, Missouri, *for Appellant*. Roger W. Yoerges, Wilmer, Cutler & Pickering, Washington, D.C., *for Appellee*.

Before NIEMEYER, LUTTIG, and TRAXLER, *Circuit Judges*.

Affirmed by published opinion. Judge TRAXLER wrote the majority opinion, in which Judge NIEMEYER joined. Judge LUTTIG wrote a concurring opinion.

OPINION

TRAXLER, *Circuit Judge*:

St. Louis University ("SLU") paid a $16 million Missouri state-court judgment to the family of a boy who became paralyzed after receiving Orimune, an oral polio vaccine, and SLU now seeks contribution from American Cyanamid Company, the parent company of the vaccine manufacturer. The district court granted summary judgment in favor of Cyanamid, and SLU appeals. We affirm.

I.

Much of the factual and procedural background relevant to this case is set out in our opinion in *St. Louis University v. United States*, 336 F.3d 294, 2003 WL 21660348 (4th Cir.2003), which is also filed today. To the extent possible, we will not repeat that information in this opinion.

After SLU paid the judgment in the state court case, it filed various federal and state-court actions against Cyanamid. These actions were dismissed for procedural reasons. SLU ultimately filed a contribution action against the United States government in federal district court in Maryland (the "Government Contribution Action"). The district court in that action granted summary judgment in favor of the government in 1999.

Cyanamid thereafter filed a declaratory judgment action in the same federal district court, seeking a declaration that the summary judgment order in the Government Contribution Action collaterally estopped SLU from seeking contribution against Cyanamid. The district court agreed with Cyanamid, gave collateral estoppel effect to its order in the Government Contribution Action, and granted summary judgment in favor of Cyanamid. SLU appealed the rulings in the declaratory judgment action and the Government Contribution Action. This court reversed and remanded both cases for further proceedings. *See St. Louis Univ. v. United States,* 5 Fed.Appx. 133 (4th Cir. 2001); *American Cyanamid v. St. Louis Univ.,* 5 Fed.Appx. 131 (4th Cir. 2001). On remand, the district court concluded that the government could be held liable in contribution to SLU, but that Cyanamid was not liable in contribution.[1]

II.

The district court concluded that SLU failed to establish that a defect in the vaccine proximately caused the injuries in the underlying state-court case. SLU's arguments on appeal largely track those it made in response to the government's appeal in *St. Louis University v. United States,*

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[1] SLU's argument that there is no live case or controversy involving Cyanamid because Cyanamid did not amend its complaint after our remand is wholly without merit. The post-remand conduct of the parties clearly indicated the question of whether Cyanamid could be held liable in contribution was tried by consent. *See People for Ethical Treatment of Animals v. Doughney,* 263 F.3d 359, 367 (4th Cir.2001) ("A party's failure to amend will not affect a final judgment if the issues resolved were tried by express or implied consent of the parties. Even without a formal amendment, a district court may amend the pleadings merely by entering findings on the unpleaded issues." (citations and internal quotation marks omitted)).

336 F.3d 294, 2003 WL 21660348 (4th Cir.2003). That is, SLU contends that the opinions of the district court and this court in the *Sabin* cases[2] are determinative of this case. The *Sabin* courts concluded that the government violated the neurovirulence regulations and that the government's actions proximately caused the injuries suffered by the *Sabin* plaintiffs, and SLU contends that the "rationale" of the *Sabin* opinions applies to Cyanamid as well as the government. Reply Brief at 6. SLU also contends that Cyanamid bears ultimate responsibility for the regulatory violations found in *Sabin,* and that these regulatory violations alone make Cyanamid liable in contribution to SLU.

As to SLU's reliance on the *Sabin* cases, we again find it to be misplaced. As we explained in our decision in No. 02-1351, the *Sabin* cases involved questions of Maryland and Florida law. Because this case is governed by Missouri law, the *Sabin* decisions are not controlling. Thus, the issue we must resolve is whether, without regard to the *Sabin* decisions, SLU has carried its burden of demonstrating that Cyanamid can be held responsible for the injures suffered by Danny Callahan. We agree with the district court that SLU did not carry this burden.

Under Missouri law, SLU is entitled to contribution from Cyanamid only if Cyanamid can be held liable for Danny's injuries. *See Gramex Corp. v. Green Supply, Inc.*, 89 S.W.3d 432, 442 (Mo.2002) (en banc). Liability is grounded in Missouri's product liability law, which follows the approach set forth in the section 402A of the

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[2] *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 743 F.Supp. 410 (D.Md.1990); *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 763 F.Supp. 811 (D.Md.1991); *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 774 F.Supp. 952 (D.Md.1991), *aff'd In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 984 F.2d 124 (4th Cir.1993) (per curiam).

Restatement (Second) of Torts. See Keener v. Dayton Elec. Mfg. Co., 445 S.W.2d 362, 364 (Mo.1969).

> The essential elements of a strict product liability claim are (1) the defendant sold a product in the course of its business; (2) the product was then in a defective condition, unreasonably dangerous when put to a reasonably anticipated use; (3) the product was used in a manner reasonably anticipated; and (4) the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold.

Lay v. P & G Health Care, Inc., 37 S.W.3d 310, 325 (Mo.Ct.App.2000); *see Restatement (Second) of Torts* § 402A(1) (1965) ("One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer. . . ."). Assuming that the first three elements are satisfied, SLU has not satisfied the fourth element, causation.

SLU has simply failed to present any competent evidence showing that the defect in the vaccine—excessive neurovirulence—proximately caused Danny's injuries.[3] SLU insists, however, that the mere fact that the neurovirulence regulations were violated entitles it to recovery. As we explained in No. 02-1351, SLU is simply

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[3] The record does include an article discussing a particular genetic mutation in the vaccine that might be connected to cases of vaccine-associated poliomyelitis, but SLU offered no expert testimony to interpret the findings and explain the relevance of the findings to this case. The article, therefore, is insufficient to satisfy SLU's burden of showing proximate cause. The expert testimony in the record is likewise insufficient. As explained in our opinion in 02-1351, none of SLU's experts testified that increased neurovirulence led to increased incidence of vaccine-associated polio, nor were any qualified to render such an opinion.

wrong on this point. Even in cases where the violation of a statute amounts to negligence *per se*, Missouri law is unambiguous in its requirement that the plaintiff must still prove that the violation proximately caused his injuries. *See Sill v. Burlington No. R.R.*, 87 S.W.3d 386, 392 (Mo.Ct.App.2002) ("If a submissible case is made under a negligence per se cause of action, a plaintiff could recover if a jury concluded that a statute was violated and the violation was the proximate cause of the injury."); *Friend v. Yokohama Tire Corp.*, 904 S.W.2d 575, 579 (Mo.Ct.App.1995) ("One of the elements of a negligence per se action is that the violation of a statute was the proximate cause of the injury.").

SLU presented no expert testimony showing that Danny Callahan would not have contracted polio or would have contracted a less severe case of polio had he been given a vaccine complying with the neurovirulence regulations. The district court, therefore, properly rejected SLU's claim against Cyanamid. *See Klein v. General Elec. Co.*, 714 S.W.2d 896, 900 (Mo. Ct. App. 1986) ("To prevail under the doctrine of strict liability in tort, the plaintiffs must prove that the product was defective and dangerous . . . that the plaintiff sustained damage as a direct result of the defect.").

Accordingly, for the foregoing reasons, the district court's grant of summary judgment in favor of Cyanamid is hereby affirmed.[4]

AFFIRMED.

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[4] Proximate cause is an element of the plaintiff's cause of action. Because SLU failed to establish this essential element of its claim, SLU's argument that Cyanamid failed to prove its entitlement to the affirmative defense set forth in comment K to section 402A of the *Restatement* is irrelevant. *See, e.g., Farm Bureau Town & Country Ins. of Missouri v. Hilderbrand*, 926 S.W.2d 944, 948 (Mo.Ct.App.1996)

LUTTIG, *Circuit Judge*, concurring:

I concur in the judgment of the court. I do not fully join the majority opinion, however, for the same reasons that I dissent from the companion case in 02-1351. Again, the majority would have it that *Sabin IV* does not present binding law for this appeal. Again, I disagree. However, I join the judgment of the court in this case for the straightforward reason that SLU failed to proffer evidence of proximate causation sufficient to satisfy the Missouri tort standards.

In contrast to the companion case, the defendant here is being sued not for its conduct as an alleged defective product-approver, but for its conduct as an alleged defective product manufacturer. The straightforward defective product manufacturing proximate cause analysis therefore applies to this case. *See Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 375-76 (Mo.1986) (en banc) (holding that the plaintiff in a product manufacturing defect case must prove the defect caused his injuries by proving that had the product been defect-free he would not have been injured).

Here, the defect in question is the defective manufacture of the vaccine. As the majority well points out, SLU proffered no evidence that the vaccine, had it been defect-free, would not have caused Danny Callahan's injuries. As such, SLU failed to create a genuine issue as

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("An affirmative defense seeks to defeat or avoid the plaintiff's cause of action. It avers that even if the petition is true, the plaintiff cannot prevail because there are additional facts that permit the defendant to avoid legal responsibility." (citation omitted)). Also irrelevant is SLU's pre-emption argument. The district court did not reject SLU's claim on pre-emption grounds, nor do we. Instead, the district court held, and we agree, that SLU failed to prove proximate cause, as required by Missouri law.

to that central proximate cause question, without which it cannot survive appellee's summary judgment motion.

For these reasons I too would affirm the district court's judgment in this case.

UNITED STATES COURT OF APPEALS
FOURTH CIRCUIT

No. 02-1351

Argued: January 22, 2003
Decided: July 16, 2003

UNITED STATES OF AMERICA,

Plaintiff-Appellant,

—v.—

ST. LOUIS UNIVERSITY, a corporation,

Defendant-Appellee.

ARGUED: Mary McElroy Leach, Senior Trial, United States Department Of Justice, Washington, D.C., *for Appellant*. Marc Simon Moller, Kreindler & Kreindler, New York, New York, *for Appellee*. ON BRIEF: Robert D. McCallum, Jr., Assistant Attorney General, Thomas M. DiBiagio, United States Attorney, Jeffrey Axelrad, Director, Torts Branch, Civil Division, United States Department Of Justice, Washington, D.C.; Daniel E. Troy, Chief, Eric M. Blumberg, Deputy Chief for Litigation, Michael N. Druckman, Associate Chief for Biologics, J.S. Food & Drug Administration, Rockville, Maryland; Alex M. Azar, II, General, Department Of

Health And Human Services, Washington, D.C., *for Appellant*. Mark R. Dunn, Herzog, Crebs & McGhee, L.L.P., St. Louis, Missouri; Stanley P. Kops, Bala Cynwyd, Pennsylvania; Rex Carr, Carr, Korein, Tillery, Kunin, Montroy & Glass, East St. Louis, Missouri, *for Appellee*.

Before NIEMEYER, LUTTIG, and TRAXLER, *Circuit Judges*.

Reversed and remanded by published opinion. Judge TRAXLER wrote the majority opinion, in which Judge NIEMEYER joined. Judge LUTTIG wrote a dissenting opinion.

OPINION

TRAXLER, *Circuit Judge*:

St. Louis University ("SLU") paid a $16 million Missouri state-court judgment to the family of a boy who became paralyzed after receiving Orimune, an oral polio vaccine. SLU sought contribution from American Cyanamid, the parent company of the vaccine manufacturer, and United States government, which tested and approved the vaccine. The district court granted summary judgment in favor of Cyanamid and the government, concluding that SLU's contribution claims were barred by principles of collateral estoppel. We reversed

and remanded. *See St. Louis Univ. v. United States*, 5 Fed.Appx. 133 (4th Cir. 2001); *American Cyanamid v. St. Louis Univ.*, 5 Fed.Appx. 131 (4th Cir. 2001). After remand, on motions and cross-motions for summary judgment, the district court concluded that the government, but not Cyanamid, was liable in contribution to SLU. The government appeals the district court's conclusion that it can be required to contribute to the state-court judgment entered against SLU.[1] We reverse and remand.

I. BACKGROUND

A. The Vaccine

There are three types of poliomyelitis; "Type I can be contracted only from a Type I virus, Type II only from a Type II virus and Type III only from a Type III virus." *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 743 F.Supp. 410, 412 (D.Md.1990). In the 1950s, an oral polio vaccine ("OPV") was developed that used a live but attenuated or weakened polio virus. "Like all vaccines cultivated from live viruses, OPV creates immunity by inducing a mild infection in the recipient." *Stuart v. American Cyanamid Co.*, 158 F.3d 622, 625 (2d Cir.1998). However, OPV also carries with it a risk that a recipient (or someone in close contact with the recipient) will contract the disease through the vaccine.

OPV is produced by passing wild virus of each type through an animal host to develop a "strain" of attenuated virus. The vaccine manufacturer uses the strain to

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[1] In *American Cyanamid Co. v. St. Louis University*, 336 F.3d 307, 2003 WL 21660347 (4th Cir. 2003), SLU appeals the district court's rejection of its contribution claim asserted against Cyanamid. We address that appeal in a separate opinion.

grow a "seed" of each type of virus, the seeds are used to produce monopools of each type of virus, and "lots" of that virus type are derived from the monopools. Lots from each type of virus are then combined into a single "trivalent" pool, from which a trivalent vaccine can be produced to protect against all three types of polio. *See Berkovitz v. United States,* 486 U.S. 531, 541, 108 S.Ct. 1954, 100 L.Ed.2d 531 (1988).

The United States government approved OPV in 1960 and in 1961 adopted regulations governing the manufacture of the vaccine. The regulations required OPV to satisfy certain "neurovirulence" tests.

> Neurovirulence is the capacity of an infectious agent to produce pathologic effects on the central nervous system. In this context, it refers to the vaccine's ability to cause paralytic poliomyelitis. The neurovirulence of a vaccine product is tested by injecting the product into monkeys. The product meets the neurovirulence criterion only if a specified number of the animals survive and a comparative analysis demonstrates that the neurovirulence of the vaccine product does not exceed the neurovirulence of a reference product previously selected by the agency.

Berkovitz, 486 U.S. at 545 n. 9, 108 S.Ct. 1954 (internal quotation marks omitted). Under the original OPV regulations, a given monopool could be used to produce vaccine only if its neurovirulence did not exceed that of the reference vaccine and the monopool was one of five consecutively made monopools that all satisfied the monkey neurovirulence test.

The government substantially amended the monkey neurovirulence regulations in 1991, in part because studies did not show a correlation between higher neurovir-

ulence scores in monkeys and the incidence of vaccine-associated polio in humans. *See Additional Standards for Viral Vaccines,* 56 Fed.Reg. 21418, 21420 (May 8, 1991) ("No single vaccine lot has been associated with an increased incidence of poliomyelitis. The lots that have been identified as associated with a case of paralytic poliomyelitis have had typically low scores when tested by FDA and the manufacturer for neurovirulence in monkeys."). In 1996, the FDA repealed a number of regulations, including the oral polio vaccine regulations. *See Revocation of Certain Regulations,* 61 Fed.Reg. 40153, 40155 (August 1, 1996).

B. The State Court Action

The state-court judgment paid by SLU arose from SLU's actions in treating 3-month old Danny Callahan. Approximately one month after receiving a dose of Orimune, Danny developed a fever and a perirectal abscess. He was treated at Cardinal Glennon Hospital by hospital and SLU employees. Although the abscess improved, Danny's legs and left arm were permanently paralyzed. Type III polio virus was isolated in Danny's stool, and doctors ultimately concluded that Danny suffered from vaccine-associated polio.

The plaintiffs' theory of the case was that SLU improperly treated Danny's abscess by giving him the wrong kind of antibiotic. The improper treatment allowed the release of endotoxins, which suppressed Danny's immune system during a time when the polio virus from the vaccine was still replicating in Danny's gastrointestinal tract. Because Danny's immune system was compromised, the attenuated polio virus in the vaccine was able to replicate fast enough to overcome his suppressed immune system, resulting in poliomyelitis.

The plaintiffs' experts testified that if the abscess had immediately been incised and drained as required by the standard of care, and if Danny had been treated with an appropriate antibiotic, the endotoxins would not have been released and his immune system would not have been suppressed. Thus, the expert witnesses testified that if Danny had been treated properly, he would not have been paralyzed by the polio vaccine. The jury's $16 million verdict in favor of the plaintiffs was affirmed by the Missouri Supreme Court. *See Callahan v. Cardinal Glennon Hosp.*, 863 S.W.2d 852 (1993) (en banc).

C. *In re Sabin*

While *Callahan v. Cardinal Glennon Hospital* was proceeding through the Missouri state courts, multi-district Orimune cases filed against the United States government under the Federal Tort Claims Act were transferred to the District of Maryland for resolution of the common legal and factual questions. *See In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 743 F.Supp. 410 (D.Md.1990); *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 763 F.Supp. 811 (D.Md.1991); *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 774 F.Supp. 952 (D.Md.1991) ("*Sabin III*").[2] The *Sabin* plaintiffs contracted polio after receiving the Orimune vaccine or after coming into contact with a recipient of the vaccine. They sued the government, alleging, *inter alia*, that the government negligently approved for release the vaccine lots which contained the doses given to the plaintiffs, even though the vaccine seeds from which the lots were derived did not meet the neurovirulence standards set forth in the governing regulations.

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[2] The district judge presiding over the cases currently before us also presided over the *In re Sabin* cases.

The district court ultimately concluded that the government could be held liable for approving vaccine lots that did not comply with the regulatory requirements for neurovirulence. Applying the "Good Samaritan" principles of the *Restatement (Second) of Torts,* the district court determined that the government, by violating its own regulatory standards and approving for release vaccine derived from seeds that exceeded the neurovirulence standards, had increased the risk of harm for those receiving the vaccine, which proximately caused the plaintiffs' injuries. *Sabin III,* 774 F.Supp. at 958. This court affirmed the district court's causation and liability determination. See *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 984 F.2d 124 (4th Cir.1993) (per curiam) ("*Sabin IV*"). The Orimune vaccine received by Danny Callahan was derived from one of the vaccine seeds that the district court in the *Sabin* cases concluded were improperly approved by the government.

II. THE CONTRIBUTION ACTION

After the Missouri Supreme Court affirmed the *Callahan* verdict, SLU filed a contribution action in Maryland against the United States, alleging that Danny Callahan's polio was caused by the governmental failings identified in the *Sabin* cases. The government moved for partial summary judgment, arguing that SLU was barred by collateral estoppel from relitigating the *Callahan* jury's conclusion that SLU's malpractice caused Danny's polio. The district court agreed, concluding that SLU was prohibited from relitigating the facts that the court believed the *Callahan* jury necessarily found in order to reach its verdict against SLU: (1) that SLU breached the applicable standard of care when treating Danny's abscess; (2) that Danny's immune system would not have been

suppressed but for SLU's inadequate treatment of the abscess; (3) that, but for the suppressed state of Danny's immune system, the live polio virus contained in the vaccine would not have been able to replicate fast enough to cause polio; and (4) that, but for SLU's negligence, Danny would not be paralyzed. The district court's collateral estoppel order prevented SLU from arguing that it was not negligent at all or that any negligence on its part did not contribute to Danny's polio, but the ruling allowed SLU to proceed on any theory consistent with the *Callahan* verdict. Thus, after the collateral estoppel order, SLU could still prevail if it could establish that an immunosuppressed child would not have contracted polio from a vaccine that complied with all regulatory requirements.

After the collateral estoppel ruling, the parties engaged in eighteen months of discovery. The government then moved for summary judgment on the ground that SLU could not prove that the government's negligence caused Danny's polio. The district court reviewed the evidence submitted by SLU and concluded that it was insufficient, given the *Callahan* findings, to establish a causal connection between the government's negligence and Danny's injuries. The district court therefore granted summary judgment to the government on SLU's contribution claim.

We reversed and remanded, concluding that the district court improperly applied Missouri law when it held that the *Callahan* jury verdict had collateral estoppel effect on SLU's contribution action against the government. We explained that Missouri law did not limit SLU to causation theories predicated on the *Callahan* jury's implicit conclusion that Danny would not have contracted polio but for SLU's negligence which resulted in the suppression of his immune system. However, the dis-

trict court had limited SLU during discovery to causation theories consistent with its ruling as to the collateral estoppel effect of the *Callahan* judgment, and the district court premised its order granting summary judgment on SLU's failure to present evidence of causation consistent with its collateral estoppel ruling. Because of the district court's error with regard to the collateral estoppel issue, we reversed the district court's grant of summary judgment to allow SLU an opportunity to develop other appropriate theories of causation.

After remand, SLU offered no new evidence, deposed no new witnesses, and offered no new theory of causation. Instead, it relied almost exclusively on the fact that in the *Sabin* cases, the court determined that the government's regulatory violations caused the injuries at issue. SLU argued that Danny Callahan's polio vaccine came from one of the seeds that the district court in *Sabin* had concluded the government negligently approved in violation of its own regulatory standards. Since the *Sabin* court had concluded that the government's failings proximately caused the injuries of the *Sabin* plaintiffs, SLU suggested that those same regulatory violations must also be held to have proximately caused Danny's injuries.

The district court agreed with SLU. Applying the same analysis the court had used in *Sabin III,* the district court concluded that the government's negligence in approving vaccine that did not satisfy the neurovirulence standards caused Danny's polio. The district court therefore granted partial summary judgment to SLU, concluding that the government was liable in contribution to SLU, but reserving for later the determination of the extent of the government's liability to SLU.[3]

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[3] The district court certified the order as appropriate for immediate review, and this court granted the government permission to bring this interlocutory appeal. *See* 28 U.S.C.A. § 1292(b) (West 1993).

III. ANALYSIS

The government's liability in contribution, of course, is dependent on SLU's ability to establish that the government can be held liable on the tort claim in the underlying action. *See United States v. Yellow Cab Co.*, 340 U.S. 543, 546-50, 71 S.Ct. 399, 95 L.Ed. 523 (1951) (concluding that the waiver of sovereign immunity under the Federal Tort Claims Act encompasses claims for contribution if the law of the relevant state would hold a private individual liable for contribution in the same circumstances); *Gramex Corp. v. Green Supply, Inc.*, 89 S.W.3d 432, 442 (Mo.2002) (en banc) ("To maintain an action for contribution, both the party seeking contribution and the defendant against whom contribution is sought must be tortfeasors, originally liable to the plaintiff-injured party." (alterations and internal quotation marks omitted)). The government contends that SLU presented no evidence showing that the government's violations of the original polio vaccine regulations proximately caused the injuries suffered by Danny Callahan. According to the government, the district court's approach to the case amounts to the imposition of absolute liability for the government, which is inconsistent with the requirements of the Federal Tort Claims Act and does not meet the causation requirements of Missouri law. Given the absence of any admissible proximate cause evidence, the government contends that the district court must have reached its decision by giving collateral estoppel effect to its decision in *Sabin III*, but that collateral estoppel cannot be applied against the government in this case.

A.

We first consider the government's arguments as to whether the decisions in the *Sabin* cases must be given controlling effect in this litigation. At the outset, we can dispense with the government's claim that the district court improperly gave collateral estoppel effect to the *Sabin* decisions, an action which might well have been error. *See United States v. Mendoza,* 464 U.S. 154, 162, 104 S.Ct. 568, 78 L.Ed.2d 379 (1984) (rejecting the use of offensive nonmutual collateral estoppel against the government). The district court expressly did not give the *Sabin* cases collateral estoppel effect. Instead, it appears that the court viewed the cases as establishing binding precedent on the question of proximate cause. *See St. Louis Univ. v. United States,* 182 F.Supp.2d 494, 500 n. 5 (D.Md.2002) ("I am not relying upon the doctrine of collateral estoppel, which may not be invocable against the government. I am simply following my reasoning in *Sabin III* that was affirmed on appeal." (citation omitted)). The question, then, is whether *Sabin III* and our decision in *Sabin IV* serve as binding precedent in this case. We think the answer to that question is no.

Under the Federal Tort Claims Act, state law, not federal law, serves as "the source of substantive liability." *FDIC v. Meyer,* 510 U.S. 471, 478, 114 S.Ct. 996, 127 L.Ed.2d 308 (1994). The Act requires the government's liability to be determined "in accordance with the law of the place where the act or omission occurred." 28 U.S.C.A. § 1346(b)(1) (West Supp.2003). The Supreme Court has concluded that the "law of the place" refers to the "whole law," including choice-of-law principles of the state where the negligent act or omission occurred. *See Richards v. United States,* 369 U.S. 1, 11, 82 S.Ct. 585, 7 L.Ed.2d 492 (1962).

Because the government's actions with regard to the polio vaccine took place in Maryland, *see Sabin III*, 774 F.Supp. at 953-54, Maryland law, including its choice-of-law principles, governs this case, just as it governed the *Sabin* cases. Under Maryland's choice-of-law principles, the law to be applied in tort cases is the law of the state where the injury was suffered, not where the negligent act occurred. *See Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 511 (4th Cir.1986). Danny Callahan was injured in Missouri, so Missouri law applies to SLU's claim against the government. But the plaintiffs in the *Sabin* cases were residents of Maryland and Florida and suffered their injuries in those states. Thus, the proximate cause determination in *Sabin III* was reached by applying Maryland and Florida law, while the proximate cause determination in this case must be made by applying Missouri law. Accordingly, notwithstanding the factual overlap of the cases, the analyses of *Sabin III* and *Sabin IV* simply do not govern this case.[4]

B.

Under Missouri law, a plaintiff seeking to hold a defendant liable in tort must establish the existence of a duty on the part of the defendant to protect the plaintiff, a breach of that duty, and damages caused by the breach. *See, e.g., L.A.C. ex rel. D.C. v. Ward Parkway Shopping Ctr. Co.*, 75 S.W.3d 247, 257 (Mo.2002) (en banc). In this case (and the *Sabin* cases), the district court con-

[4] Even assuming that SLU is correct in its contention that the tort laws of Maryland and Missouri are similar, it makes little sense for this court to apply Missouri law by way of *Sabin III* and *Sabin IV*, cases that applied Maryland and Florida law. Instead, we will go directly to the source and consult Missouri cases to determine whether SLU has satisfied the requirements of Missouri law.

cluded that the government's duty arose under the "Good Samaritan" doctrine, through which liability may be imposed for the negligent execution of voluntarily undertaken duties. *See Hoover's Dairy, Inc. v. Mid-America Dairymen*, 700 S.W.2d 426, 432-33 (Mo.1985) (en banc) (following Good Samaritan standards set forth in *Restatement (Second) of Torts* §§ 323, 324A (1965)). For purposes of this litigation, the government has agreed to be bound by the findings in the *Sabin* cases that it breached its duty by violating the OPV regulations. *See St. Louis Univ.*, 182 F.Supp.2d at 498. Thus, the only issue before the district court was whether SLU could establish that Danny Callahan's injuries were caused by the government's breach of duty.

The district court concluded that SLU had sufficiently established that the government's regulatory violations caused Callahan's injuries. The court explained that in *Sabin III*,

> I held that proximate cause was established by the mere fact that if seeds 45 B 85 and 45 B 165 had not been in use, the vaccine giving rise to the injuries would not have been manufactured. The evidence clearly establishes that but for the United States's negligence, the seeds would not have been used. I went on to reject an ancillary contention made by the government that proximate cause was dispelled by the fact that the specific lots involved in the two cases under consideration had met the regulatory neurovirulence criteria, and I concluded that the causal connection between the regulatory violations and plaintiffs' injuries are logical, sensible and direct. The Fourth Circuit affirmed this holding on appeal.
>
> My reasoning in *Sabin III* is equally applicable here. This can be most easily seen by hypothesizing

> that SLU is correct in contending that the immunosuppression allegedly caused by its malpractice played absolutely no role in making Callahan susceptible to contracting polio from OPV. If that is true, Callahan stands in exactly the same position as did the plaintiffs in other *Sabin* cases because in that event the sole cause of his polio was the vaccine. Likewise, even if the immunosuppression did play some role in the disease process, Callahan's exposure to the oral vaccine had to be a contributing cause to his paralysis. The isolation of Type III polio virus in Callahan's stool demonstrates he contracted polio, and no one suggests that the immunosuppression alone could have caused the disease. Accordingly, as I held in *Sabin III*, Callahan was exposed to the virus as a consequence of the government's violation of the OPV regulations. If the government had not wrongfully approved the seed from which the vaccine was derived, Callahan would never have been administered a dose of Orimune and would never have contracted polio even if he had been immunosuppressed. This "but for" relationship meets the standard of proximate cause under Missouri law just as it does under the law of Maryland and Florida applicable in *Sabin III*.

St. Louis Univ., 182 F.Supp.2d at 499-500 (footnotes, alterations, and internal quotation marks omitted).

We assume, of course, that *Sabin III* and *Sabin IV* properly applied Maryland and Florida law.[5] Nonethe-

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[5] The government points out that when this court in *Sabin IV* affirmed the proximate cause analysis in *Sabin III*, we relied on *Waffen v. United States Department of Health & Human Services*, 799 F.2d 911 (4th Cir.1986), which considered causation requirements under Maryland law in the context of a claim for loss of chance of survival. Subsequent cases from this court and Maryland state courts

less, it is clear that the approach taken in the *Sabin* cases is inconsistent with the requirements of Missouri law, which governs this case. Under Missouri law, a plaintiff must establish both causation-in-fact and proximate cause. *See Callahan*, 863 S.W.2d at 862, 865; *Robinson v. Missouri State Highway & Transp. Com'n*, 24 S.W.3d 67, 77 (Mo.Ct.App.2000) (per curiam).

> A defendant's conduct is the cause in fact of a plaintiff's injuries where the injuries would not have occurred but for that conduct. Proximate cause is not causation in fact, but is a limitation the law imposes upon the right to recover for the consequences of a negligent act. The requirement of proving proximate cause absolves those actors whom it would be unfair to punish because of the attenuated relation which their conduct bears to the plaintiff's injury.

Robinson, 24 S.W.3d at 77 (citations and internal quotation marks omitted). The district court's conclusion that Danny Callahan would not have contracted polio "but for" the government's action thus goes only to the question of causation-in-fact, not proximate cause, because it does not answer the question of whether the particular result that occurred was a reasonable and probable consequence of the government's conduct. *See*

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have indicated that *Waffen* did not accurately articulate the contours of Maryland's proximate cause requirements. *See Hurley v. United States*, 923 F.2d 1091, 1096 (4th Cir.1991) ("Our interpretation of Maryland law in *Waffen* is called into question because we were interpreting Maryland law as espoused in *Hetrick v. Weimer*, which was later reversed by the Maryland Court of Appeals." (footnote omitted)); *Cooper v. Hartman*, 311 Md. 259, 533 A.2d 1294, 1297 & n. 4 (1987) (placing *Waffen* among a group of decisions that improperly "relaxed the standards regarding causation").

Callahan, 863 S.W.2d at 865 (Missouri courts "have generally said that the injury must be a reasonable and probable consequence of the act or omission of the defendant.").

The district court's explanation of why different results were required as to the claims against the government and Cyanamid, the vaccine manufacturer, suggests that the court believed the causation standard is different in cases where the duty arises under the Good Samaritan doctrine. The court stated:

> I find that Cyanamid cannot be held liable for contribution to SLU and that it is therefore entitled to summary judgment. While I recognize that this holding may seem asymmetrical, paradoxical, or even perverse in light of my finding that the government is liable for contribution, the difference in result flows from the difference in the nature of the respective duties owed by the United States and Cyanamid to those who were exposed to the live virus contained in OPV.
>
> As indicated above, in *Sabin III* I ruled that the Good Samaritan doctrine and its parallel provision, *Restatement (Second) of Torts* § 323, imposed upon the government the duty not to approve vaccine seeds in violation of the OPV regulations. Cyanamid was under no such duty. Its duties and responsibilities to the members of the public, particularly to OPV recipients and their families, [are] defined by products liability law. In considering claims against Cyanamid, the focus must therefore be on the safety of its product, not the regulatory process for which the government bore responsibility. Likewise, in analyzing the element of proximate cause in claims against Cyanamid, the focus must be on whether the

> plaintiff can prove that it was a defect in the OPV that resulted in his injury, not simply—as in a case against the government—whether he had been exposed to OPV derived from a seed that had been improperly approved in violation of the regulatory process. Under Missouri law this element of causation is required whether a plaintiff sues for strict liability, negligence, or breach of warranty.

St. Louis Univ., 182 F.Supp.2d at 500. Missouri law, however, makes it quite clear that the Good Samaritan doctrine is relevant to the question of duty only; it has no effect on the general rules of causation. *See Wollen v. DePaul Health Center,* 828 S.W.2d 681, 683 (Mo.1992) (en banc) ("[T]his Court has recognized that section 323 [of the *Restatement (Second) of Torts*] creates a duty of care. In creating this duty, this section of the Restatement defines a type of negligent behavior but does not alter the rules of causation." (citation omitted)). Thus, SLU's claim against the government requires evidence of proximate cause in addition to evidence of but-for causation.

As to proximate cause, we note that all OPV, including OPV that satisfied all regulatory requirements, carried the risk that the recipient would actually contract polio. Therefore, to show that Danny's polio was caused by the government's regulatory violations, we conclude that SLU was required to establish that Danny likely would not have contacted polio (or would have contracted a less severe case of polio) from a vaccine that satisfied the government's neurovirulence requirements. Any lesser standard would result in the government being held strictly liable for its regulatory violations, which would be inconsistent with Missouri law. *See Sill v. Burlington No. R.R.*, 87 S.W.3d 386, 392 (Mo.Ct.App.2002) (explaining that the violation of a

statute can, under certain circumstances, support a negligence *per se* claim, but that the plaintiff must prove that the statutory "violation was the proximate cause of the injury."). And this evidence, of course, must be in the form of expert testimony. *See, e.g., Wright v. Barr,* 62 S.W.3d 509, 524 (Mo.Ct.App.2001) ("If there is a sophisticated injury, one that requires surgical intervention or other highly scientific techniques for diagnosis, expert medical testimony is required to prove causation.").

There is no such evidence in this record. At best, SLU's experts assumed that increased neurovirulence led to increased incidence of vaccine-associated polio, but SLU's experts did not offer that opinion. In fact, none of SLU's experts were even qualified to render such an opinion.[6] The district court recognized this absence of evidence, *see St. Louis Univ.,* 182 F.Supp.2d at 502 ("Whether or not an oral polio vaccine that complied with the OPV regulations would have caused Callahan and the plaintiffs in the other *Sabin* cases to contract polio ultimately is unknowable and unprovable."), as does SLU. SLU, however, insists that it is not required to present evidence of proximate cause.

According to SLU, the regulations establishing the neurovirulence standards created an "unrebuttable presumption" that any vaccine exceeding the standards posed an unacceptable risk that the recipient would contract polio. Brief of Appellee at 21. Thus, SLU contends

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[6] In the first appeal, this court noted that there was some evidence that a more neurovirulent vaccine caused Danny to have a more severe case of polio. SLU, however, did not pursue this theory after remand and does not pursue it on appeal. Moreover, the district court concluded that the expert who provided this testimony was not qualified to render an opinion on causation, and SLU does not challenge that determination on appeal.

that once it was established in the *Sabin* cases that the government violated its regulations and that the violations proximately caused the injuries, the government was automatically liable for the injuries suffered by anyone who received a vaccine derived from one of the vaccine seeds at issue in the *Sabin* cases. As noted above, such an approach is utterly inconsistent with Missouri law. *See Sill,* 87 S.W.3d at 392 ("If a submissible case is made under a negligence *per se* cause of action, a plaintiff could recover if a jury concluded that a statute was violated and the violation was the proximate cause of the injury."); *Friend v. Yokohama Tire Corp.,* 904 S.W.2d 575, 579 (Mo.Ct.App.1995) ("One of the elements of a negligence *per se* action is that the violation of a statute was the proximate cause of the injury.").

Because there is no evidence that the government's regulatory violations proximately caused Danny's injury, SLU has failed to show that it is entitled to contribution from the government. We therefore reverse the district court's grant of partial summary judgment in favor of SLU and we remand for the entry of judgment in favor of the government. *See Monahan v. County of Chesterfield, Va.,* 95 F.3d 1263, 1265 (4th Cir.1996) (explaining that where cross-motions for summary judgment have been filed, the appellate court can direct the entry of judgment in favor of the appellant).

REVERSED AND REMANDED.

LUTTIG, *Circuit Judge*, dissenting:

I would affirm the district court's judgment in this case under the binding precedent of the circuit. In *In re Sabin Oral Polio Vaccine Products Liability Litigation,*

984 F.2d 124 (4th Cir.1993) ("*Sabin IV*"), we determined that under a tort regime, identical in all relevant respects to the one at issue here, an injury, identical to the one at issue here, was proximately caused by tortious conduct identical to that alleged here. On the basis of the *reasoning* which we adopted in that case, I must conclude that our application here of Missouri state law yields the conclusion that appellee SLU proffered sufficient evidence to establish the legally necessary causation for it to prevail.

The majority reaches the opposite conclusion. It reasons that "our decision in *Sabin IV* [does not] serve as binding precedent in this case," *ante* at 300, because "the proximate cause determination in *Sabin III* was reached by applying Maryland and Florida law, while the proximate cause determination in this case must be made by applying Missouri law." *Ante* at 300. This reasoning would be compelling if SLU proposed that we apply the *state law holdings* of *Sabin IV* to the facts of the case before us today. But, the majority is wrong to suggest that SLU, or by implication, I, argue that *Sabin IV* is binding as a matter of Missouri state law. All that SLU asks, and all that I contend is appropriate, is that we reach our judgment by applying the binding *reasoning* of *Sabin IV.*

While our decision in *Sabin IV* resulted in state law holdings, it also produced reasoning, by which we reached those state law holdings. This reasoning is uniquely the creature of this court, and, as it is binding upon us, we must apply it in other cases involving the same predicate facts (*i.e.*, functionally identical underlying tort regime, facts, and causation theories). In this manner, *Sabin IV* binds us as a matter of federal law, delimiting the open field that we would otherwise face in formulating our reasoning. Because the question before

us is simply how we will reason to our application of Missouri's tort regime, which regime is functionally identical in the relevant regards to those from which we reasoned in *Sabin IV,* our conclusion as to how to reason to this application is governed by *Sabin IV.*

The majority, to its credit, does not attempt to deny the crucial point in this case, namely, that in *Sabin IV* we reasoned from two state tort law regimes, from injuries, and from asserted causation theories, that were functionally indistinguishable from those before us today. But, absent such a denial, it has no basis on which to reach the conclusion it reaches today other than that it disagrees with the reasoning we adopted in *Sabin IV.* While I am somewhat sympathetic to the critique the majority implicitly levels at that reasoning, the majority, as am I, is bound to abide by it until this court *en banc* or the Supreme Court holds otherwise.

Having mistakenly rejected the authority of *Sabin IV,* the majority asserts that the district court erred here because it engaged in no proximate cause determination whatsoever. But *Sabin IV* quite clearly shows the majority to be in error on this point. There, we concluded that an identical causation theory, in the unique circumstance where the tortfeasor's function is that of a product-approver, suffices to establish proximate cause. We reasoned as follows:

> The final point of appeal concerns the district court's determination that [the government's] *approval* of the lots was the *proximate cause* of [the plaintiff's] injuries. The test of probable [sic] cause is one of "reasonable probability or reasonable certainty." In other words, "the plaintiff has the burden of introducing evidence which affords a reasonable basis for the conclusion that it is more likely than

not that the conduct of the defendant was a substantial factor in bringing about the result."

The district court concluded:

> Regardless of the acceptability of the specific lots from which were derived the vaccine . . . if [the government] had properly applied 42 C.F.R. § 73.114(b)(1)(iii) . . . the seed would not have been used. This is so because the manufacturer would have been unable to satisfy the consistency requirement found in 42 C.F.R § 73.116(c). Likewise, regardless of the acceptability of the lots from which the vaccine administered to [the plaintiff] were derived, the lots would never have been produced and released but for the approval of [the] seed. . . . Thus, the causal connections between the regulatory violations and plaintiffs' injuries are logical, sensible and direct.
>
> The government's argument that the failure to amend the regulation was not the *proximate cause* of the plaintiff's injuries misconstrues the plaintiff's claims and the district court's opinion. [The government's] liability arose out of releasing vaccine in violation of the regulations, not in its failure to amend the regulations.

Sabin IV, 984 F.2d at 128 (emphasis added) (citations omitted).

By this passage, we clearly concluded that the district court's reasoning—what the majority here terms a merely but-for causation analysis—constituted a proper *proximate* cause analysis with respect to a tortfeasor who functions as a unilateral product-approver. Under this binding precedent, we are required to conclude that the

district court's identical reasoning here is likewise a proper proximate cause analysis.

The majority's underlying dissatisfaction with this analysis seems based on the belief that such an analysis "would result in the government being held strictly liable for its regulatory violations, which would be inconsistent with Missouri law." *Ante* at 303. As an initial matter, strict liability effects culpability standards (*e.g.*, negligence, recklessness, etc.), *not* causation standards. That every regulatory violation in the circumstance where the government is a product-approver is the proximate cause of injuries sustained by the use of the defectively approved product simply does not create strict liability since under Missouri law it still must be proven that the violation was the result of negligence or recklessness.

And, while I am somewhat sympathetic to the majority's other apparent concern—that the government is treated differently than the manufacturer with regards to the causal effect of its action in Callahan's injury—we may not base our judgment on it, for it is quite clear that we have already concluded that the district court's analysis, distinguishing between the two parties' causal effects, was proper. And this determination binds us, regardless of whether our prior reasoning as to why it is so is persuasive.

The majority's concern on this score, however, is not even fully borne out. That the causal effect of the government's conduct is differently understood than that of the manufacturer is the result of the fact that the government's role as tortfeasor here springs from its actions as a product-approver. As opposed to a manufacturer, who presumably sells a range of product, some with and some without defect, a product-approver's *only* role is to determine whether a particular product goes to market at

all. In this unique role, failure, and breach of a duty of care, does not result in any easy comparison between what would have happened had the defective "product" not been defective, because, for such a tortfeasor, the defective "product" is the failure to withhold *completely* the distributed item from distribution. Thus, had the government's "product" been free of defect, none of the offending vaccine would have been distributed at all. This contrasts with the case of a manufacturer who, had its product been defect free, would have distributed a defect free product. The causation of injury by one's "defective" action is quite different from the other, since one's "defect-free" action keeps all product from the market while the other instead distributes defect-free product. Since Florida and Maryland law, just like Missouri law, require plaintiffs to prove proximate cause by demonstrating that, had the product been defect-free, the injury would not have occurred, and since the government's defect-free product would have been the complete withholding of the vaccine, it was not too great of a stretch, even if not wholly persuasive, for us to conclude in *Sabin IV* that the alleged conduct proximately caused the alleged injury.

The district court's notation that its causation analysis took into account that the government acted under a Good Samaritan duty articulates this aspect of the case. That the majority instead thinks this notation signals that the lower court mistakenly "believed the causation *standard* is different in cases where the duty arises under the Good Samaritan doctrine[,]" *ante* at 302 (emphasis added), illustrates the panel's failure to appreciate how a manufacturer's defect causes injury in one way, while defective product approval causes injury in another. That different causal relationships exist between different categories of conduct and the injury they cause bespeaks

nothing as to what legal standard applies to those causal relationships in a tort action.

But even if there were any merit to the majority's concerns that our prior analysis effectively creates a strict liability culpability standard or a but-for causation standard and treats the government differently from the manufacturer, those issues have already been fought over and decided—and not by today's opinion. *Sabin IV* decided the matter and so provides binding reasoning, which, if we were to apply it today, would result in affirmance of the district court's judgment. Indeed, the rule we face not only binds us, but also every district court within our circuit and every future panel of our court, and the dissent's judgment only evades that reality temporarily. *See Booth v. Maryland,* 327 F.3d 377, 382-83 (4th Cir.2003) (explaining that it is error to follow the more recent of two contradicting panels).

For these reasons, I respectfully dissent.

UNITED STATES DISTRICT COURT
D. MARYLAND

Nos. CIV.JFM-95-CV-3639,
CIV.JFM-99-CV-1316

January 25, 2002

ST. LOUIS UNIVERSITY,

Plaintiff,

—v.—

THE UNITED STATES,

Defendant.

AMERICAN CYANAMID CO.,

Plaintiff,

—v.—

ST. LOUIS UNIVERSITY,

Defendant.

Raymond F. Altman, Baltimore, MD, Marc S. Moller, Henry Gluckstern, Kreindler & Kreindler, New York City, Rex Carr, Carr, Korein, East St. Louis, IL, Stanley

P. Kops, Kops & Fenner, Philadelphia, PA, P. Terrence Crebs, Herzog, Crebs & McGhee, St. Louis, MO, *for St. Louis University*.

Perry F. Sekus, Lynne A. Battaglia, U.S. Attorneys Office, Baltimore, MD, Mary McElroy Leach, Frank Hunger, U.S. Dept. of Justice, Washington, DC, *for U.S.*

Roger W. Yoerges, Wilmer, Cutler and Pickering, Washington, DC, David P. Donovan, Wilmer Cutler and Pickering, Tysons Corner, VA, *for American Cyanamid Co.*

MEMORANDUM

MOTZ, *District Judge*.

These two related cases may be the last involving the Sabin oral polio vaccine that was the subject of MDL proceedings before me. *See In re Sabin Oral Polio Vaccine Prod. Liab. Litig.*, 743 F.Supp. 410 (D.Md.1990) ("*Sabin I*"); 763 F.Supp. 811 (D.Md.1991) ("*Sabin II*"); 774 F.Supp. 952 (D.Md.1991) ("*Sabin III*"). They arise from a $16 million judgment obtained by Danny Callahan in a medical malpractice action instituted against St. Louis University ("SLU") in Missouri. After the judgment was affirmed on appeal by the Missouri Supreme Court, SLU instituted an action against the United States in this court for contribution, contending that the paralysis from which Callahan suffers was caused by his having been administered a dose of vaccine derived from a seed I found in the MDL proceedings to have been wrongfully approved by the government. SLU instituted a similar action in Missouri against American Cyanamid ("Cyanamid"), the parent of Lederle Laboratories, the manufacturer of the vaccine. SLU eventually consented

to the dismissal of that action after extensive discovery had been conducted. In April 1999, I granted a motion for summary judgment in favor of the United States against SLU. In the wake of that decision, Cyanamid filed a declaratory action against SLU, and I entered summary judgment in its favor as well. SLU appealed from both decisions. The Fourth Circuit reversed my rulings and remanded the cases for further proceedings.

Although no further discovery has been conducted after remand, the parties have agreed that renewed summary judgment motions are appropriate. In its action against the United States, SLU has moved for partial summary judgment on the issues that the government was negligent and that its negligence was at least one of the proximate causes of Callahan's paralysis. The United States also has requested summary judgment. Similarly, Cyanamid has filed a summary judgment motion in its declaratory judgment action against SLU.

I.

The relevant background facts concerning the underlying *Callahan* action, the *Sabin* MDL proceedings, and the prior history of SLU's contribution action against the United States were succinctly stated by the Fourth Circuit in its opinion reversing my ruling in the case against the United States. 5 Fed.Appx. 133, 136-37 (4th Cir. 2001). That opinion was not published in the Federal Reporter, and I will take the liberty of quoting from it verbatim:

> A. The State Court Action
>
> In 1978, three-month-old Danny Callahan received a dose of Orimune, an oral vaccine containing an attenuated strain of a live polio virus. Approxi-

mately one month later, Danny developed a perirectal abscess that was treated by employees of Cardinal Glennon Hospital and SLU. The abscess was not drained and no culture was taken to determine if the infection was caused by gram positive or gram negative bacteria. Danny was given an antibiotic that was effective only on gram positive bacteria. After several days, Danny's condition had not improved, and his mother noticed that his legs appeared to be "floppy." His parents took him back to the hospital, where the abscess was incised and drained. Cultures of the abscess revealed four types of gram negative bacteria, and Danny was given an antibiotic that was effective against those organisms. Although the abscess improved, Danny's legs and left arm remained paralyzed. Type III polio virus (the type in the vaccine dose he had received) was isolated in Danny's stool, and, although some experts disagree, it appears that Danny suffers from vaccine-associated polio.

The Callahans filed a medical malpractice action against SLU, Cardinal Glennon, and American Cyanamid Company, parent company of the manufacturer of the vaccine. At the time of trial, only SLU and Cardinal Glennon remained as defendants. The Callahans' expert witnesses testified that Danny's paralysis was caused by the negligence of SLU and Cardinal Glennon in failing to treat the abscess properly when Danny was first brought to the hospital. According to the experts, the improper treatment allowed endotoxins to be released, which suppressed Danny's immune system. Because Danny's immune system was compromised, the attenuated polio virus contained in the vaccine was able to replicate fast enough to overcome his sup-

pressed immune system, resulting in poliomyelitis. The Callahans' experts testified that if the abscess had been treated properly from the outset, the endotoxins would not have been released, his immune system would not have been suppressed, and he would not have contracted polio.

SLU and Cardinal Glennon, however, presented evidence that Danny's paralysis was not connected to the abscess and that it was caused by the attenuated polio virus in the vaccine mutating to a virulent form after it had been ingested. They presented evidence showing that in the 1980s approximately one in four hundred thousand people receiving Orimune developed polio. Their experts also testified that the Callahans' theory that endotoxins suppress the immune system making a host more susceptible to vaccine-induced poliomyelitis was not supported by any known research.

The jury returned a $16 million verdict against SLU and Cardinal Glennon. After the trial, Cardinal Glennon entered into a settlement agreement with the Callahans. SLU appealed, and the jury's verdict was affirmed by the Missouri Supreme Court sitting en banc. *See Callahan v. Cardinal Glennon Hosp.*, 863 S.W.2d 852 (Mo.1993) (en banc).

B. *In re Sabin*

While the *Callahan* case was winding its way through the Missouri court system, multi-district Orimune cases filed against the United States government under the Federal Tort Claims Act were transferred to the District of Maryland for resolution of the common legal and factual questions. . . .

> The plaintiffs in the *In re Sabin* cases contracted polio after receiving a Type III Orimune vaccine or after coming into contact with a recipient of the Type III vaccine. They sued the government, alleging, inter alia, that the National Institute of Health's Division of Biologic Standards negligently issued a license to Lederle Laboratories (a subsidiary of American Cyanamid) to manufacture the vaccine and improperly approved vaccine that did not meet the "neurovirulence" standards set forth in the governing regulations. The district court ultimately concluded that the government violated the governing regulations and was negligent in approving certain vaccine "seeds" and the release of lots derived therefrom and that its negligence was a proximate cause of the injuries suffered by the plaintiffs, who received or were exposed to vaccines from lots derived from the improperly approved seeds. *See* 774 F.Supp. at 957-58, 763 F.Supp. at 821-25. The district court's *Sabin* opinions were affirmed by this Court on appeal. *See In re Sabin Oral Polio Vaccine Prod. Liab. Litig.*, 984 F.2d 124 (4th Cir.1993) (per curiam). The Orimune vaccine received by Danny Callahan was derived from one of the vaccine seeds that the *In re Sabin* cases concluded were improperly approved by the government. . . .

5 Fed.Appx. at 136-37.

II.

After stating these background facts, the Fourth Circuit went on to decide that I erred in holding that under Missouri law (which undisputably is applicable here) the findings adverse to SLU in the *Callahan* case would have a collateral estoppel effect in a subsequent contri-

bution action. In effect, the Fourth Circuit held that SLU was free to present in a contribution action the defense it had lost in *Callahan,* i.e., that its alleged malpractice in improperly treating Callahan's abscess was immaterial because known research does not support the opinion expressed by Callahan's experts that endotoxins suppress the immune system, making a host more susceptible to vaccine-induced polio.

SLU acknowledges that the invalidity of the immunosuppression theory has not yet been established in this case, and it is not moving for complete summary judgment on the ground that its own negligence was *de minimis* or nil. It is seeking only a ruling that the United States was negligent and that the negligence was at least one of the proximate causes resulting in Callahan's paralysis. The United States has agreed to be bound in this litigation by the regulatory violations that were found to exist in *Sabin II.* (United States' Opp'n at 2.) It also has stipulated to owing a duty of care to Callahan.[1] (*Id.* at 15.) Although it stipulates to duty and to the regulatory violations, the United States does not admit to proximate cause.

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[1] In *Sabin III,* I applied the Good Samaritan doctrine of the Restatement (Second) of Torts § 324A (1965) as the source of the duty the government owed to the plaintiffs, parents who had contracted polio from shed virus after their children were administered vaccine. 774 F.Supp. at 954. I noted that in cases, such as this one, in which persons contracted polio as the result of vaccine administered directly to them, the source of duty is found in a parallel provision, Restatement (Second) of Torts § 323 (1965). *Id.* at 954 n. 5. That provision covers situations in which a tortfeasor renders services to another and, by failing to exercise reasonable care, causes injury to that person. *See id.* Missouri has adopted § 323 as part of its tort law. *See Stanturf v. Sipes,* 447 S.W.2d 558, 561-62 (Mo.1969); *Strickland v. Taco Bell Corp.,* 849 S.W.2d 127, 132 (Mo.Ct.App.1993).

In my original opinion I found that "none of SLU's experts have expressed an opinion that, if Callahan had been given a vaccine that satisfied the neurovirulence requirements of the applicable regulations, he would not have contracted polio."[2] SLU has not supplemented the record on this point in any respect, and I adhere to that finding. The United States contends that the absence of any such opinion is fatal to SLU's claims since in order to establish proximate cause, SLU must prove that Callahan contracted polio as the result of excessive neurovirulence in vaccine derived from a seed that had been wrongfully approved. Stated conversely, according to the United States, SLU must prove that vaccine derived from a seed meeting regulatory requirements would not have had the same effect as did the vaccine that Callahan received.

The United States made a similar argument in *Sabin III*, and I found it unpersuasive. I held that proximate cause was established by the mere fact that "if . . . [seeds 45 B 85 and 45 B 165[3] had not been in use, the

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[2] In its initial opinion the Fourth Circuit held that this finding was erroneous because Robert Baltimore, one of SLU's experts, had "stated that, in his opinion, an excessively neurovirulent vaccine would produce more severe paralysis than would a vaccine that complied with all regulatory requirements." However, on April 25, 2001, after the United States filed a petition for clarification or rehearing pointing out that SLU had represented that it was not offering Dr. Baltimore as an expert on neurovirulence, the court issued an order stating that "the panel opinion should not be construed as determining the admissibility of any expert testimony. The District Court is free to consider *de novo* any evidentiary issues that might be raised on remand." SLU has not attempted to broaden the area of Dr. Baltimore's proffered expertise. Therefore, I continue to find, as I did originally, that nothing he has opined is sufficient to establish that a vaccine complying with the regulations would not have caused Callahan to contract polio.

[3] The vaccine administered to Callahan was derived from seed 45 B 85.

vaccine giving rise to the injuries would not have been manufactured. The evidence clearly establishes that but for . . . [the United States's] negligence, the seeds would not have been used." 774 F.Supp. at 958. I went on to reject an ancillary contention made by the government that proximate cause was dispelled by the fact that the specific lots involved in the two cases under consideration had met the regulatory neurovirulence criteria, and I concluded that "the causal connection between the regulatory violations and plaintiffs' injuries are logical, sensible and direct." *Id.* The Fourth Circuit affirmed this holding on appeal.

My reasoning in *Sabin III* is equally applicable here.[4] This can be most easily seen by hypothesizing that SLU is correct in contending that the immunosuppression allegedly caused by its malpractice played absolutely no role in making Callahan susceptible to contracting polio from OPV. If that is true, Callahan stands in exactly the same position as did the plaintiffs in other *Sabin* cases because in that event the sole cause of his polio was the vaccine. Likewise, even if the immunosuppression did play some role in the disease process, Callahan's expo-

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[4] It might appear that I am modifying the view I originally took in this case that SLU's case was critically flawed by the absence of evidence that a less virulent vaccine would not have caused Callahan's paralysis. The context in which I expressed that view was, however, substantially different from the one now presented. As I have already indicated, in my original opinion I held that my collateral estoppel ruling foreclosed SLU from relying on the opinion of its experts that it had not been negligent at all and that the Orimune administered to Callahan had been the sole cause of his polio. I further found that because of that holding the only way that SLU could prevail would be to render its own negligence immaterial by proving that a less neurovirulent vaccine would not have caused a person in an immunosuppressed state to contract polio. The Fourth Circuit's decision has mooted this line of reasoning.

sure to the oral vaccine had to be a contributing cause to his paralysis. The isolation of Type III polio virus in Callahan's stool demonstrates he contracted polio, and no one suggests that the immunosuppression alone could have caused the disease. Accordingly, as I held in *Sabin III,* Callahan was exposed to the virus as a consequence of the government's violation of the OPV regulations. If the government had not wrongfully approved the seed from which the vaccine was derived, Callahan would never have been administered a dose of Orimune and would never have contracted polio even if he had been immunosuppressed. This "but for" relationship meets the standard of proximate cause under Missouri law just as it does under the law of Maryland and Florida applicable in *Sabin III. See Callahan,* 863 S.W.2d at 860-61 (explaining that "but for" causation means that " 'the defendant's conduct is a cause' of the event if the event would not have occurred 'but for' that conduct") (*quoting Prosser and Keeton on Torts* § 41 (5th ed.1984)); *Martin v. City of Washington,* 848 S.W.2d 487, 493 (Mo.1993) (en banc) (describing the "simplest test for proximate cause" as "whether the facts show that the injury would not have occurred in the absence of the negligent act"); *Bauman v. Conrad,* 342 S.W.2d 284, 287 (Mo.Ct.App.1961) ("The proof must show that had the negligence not occurred, the . . . plaintiff's injuries would not have occurred.").[5]

For these reasons, I find that the United States is liable in contribution because its violations of its own regula-

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[5] I should point out that in ruling against the United States on this issue, I am not relying upon the doctrine of collateral estoppel, which may not be invocable against the government. *See United States v. Mendoza,* 464 U.S. 154, 162, 104 S.Ct. 568, 78 L.Ed.2d 379 (1984). I am simply following my reasoning in *Sabin III* that was affirmed on appeal.

tions constituted negligence and were a proximate cause of Callahan's paralysis. I am not making any determination as the extent of that liability. If I ultimately conclude that Callahan likely would not have contracted polio but for SLU's failure to make a proper diagnosis and treatment of his abscess, SLU will be subject to a substantially greater share of liability than the United States. If, on the other hand, Callahan's immunosuppression was, as SLU contends, merely coincidental and not a material factor in causing him to contract polio, the greater share of liability will fall upon the United States. Resolution of these issues must await the development of a full factual record.

III.

I will now turn to the issues raised by Cyanamid's declaratory judgment action. I find that Cyanamid cannot be held liable for contribution to SLU and that it is therefore entitled to summary judgment. While I recognize that this holding may seem asymmetrical, paradoxical, or even perverse in light of my finding that the government is liable for contribution, the difference in result flows from the difference in the nature of the respective duties owed by the United States and Cyanamid to those who were exposed to the live virus contained in OPV.

As indicated above, in *Sabin III* I ruled that the Good Samaritan doctrine and its parallel provision, Restatement (Second) of Torts § 323, imposed upon the government the duty not to approve vaccine seeds in violation of the OPV regulations. Cyanamid was under no such duty. Its duties and responsibilities to the members of the public, particularly to OPV recipients and their families, is defined by products liability law. In

considering claims against Cyanamid, the focus must therefore be on the safety of its product, not the regulatory process for which the government bore responsibility. Likewise, in analyzing the element of proximate cause in claims against Cyanamid, the focus must be on whether the plaintiff can prove that it was a defect in the OPV that resulted in his injury, not simply—as in a case against the government—whether he had been exposed to OPV derived from a seed that had been improperly approved in violation of the regulatory process. Under Missouri law this element of causation is required whether a plaintiff sues for strict liability, negligence, or breach of warranty. *See, e.g., Bone v. Ames Taping Tool Sys., Inc.*, 179 F.3d 1080, 1081 (8th Cir.1999) ("Under Missouri law, to prevail on a claim of strict liability, negligence, or breach of warranty, [plaintiff] must prove that his use of the [defendant's product] directly caused or contributed to cause some or all of his injuries."); *Chism v. W.R. Grace & Co.*, 158 F.3d 988, 991 (8th Cir.1998) (explaining that for negligence or strict liability claims under Missouri law, a plaintiff must establish a causal connection between the defendant's conduct and the plaintiff's injury); *Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 375-76 (Mo.1986) (en banc) (holding that the plaintiff in a strict liability product defect case must show that the defect caused his injuries); *Mothershead v. Greenbriar Country Club, Inc.*, 994 S.W.2d 80, 89 (Mo.Ct.App.1999) (requiring proof of causal link between product defect and injury in failure to warn case).

Product safety regulations certainly may provide a reference point in defining the standard of conduct a manufacturer must meet in fulfilling its duty to consumers

under products liability law.[6] Likewise, violations of safety regulations may subject a manufacturer to governmental enforcement action, including criminal prosecution under appropriate circumstances. However, such violations do not provide themselves provide a basis for a private right of action independent of general tort principles. *See In re Orthopedic Bone Screw Prod. Liab. Litig.*, 193 F.3d 781, 791-92 (3d Cir.1999). Moreover, although I recognize that at least one court has concluded to the contrary, *see Campagna v. American Cyanamid Co.*, 337 N.J.Super. 530, 767 A.2d 996 (2001), I am of the view that violation of the OPV regulations is not sufficient to prove the element of proximate cause in a context, such as that presented by SLU's claims against Cyanamid, where a plaintiff must prove that it is more likely than not that it was excessive neurovirulence in a dose of vaccine that caused him to contract polio. The regulatory criteria were developed entirely from monkey neurovirulence tests and, as the absence of any proffered expert testimony by SLU affirms, the results of those tests alone are not sufficient

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[6] It might be noted that in this case reference solely to the literal language of the OPV regulations as setting the substantive standard of care in a products liability action would be problematical since the persons responsible for enforcement of the regulations (including some of the best scientists in the United States) had concluded that the safety standards the regulations embodied were unreasonably high. Indeed, that was the very reason they approved seeds whose test results did not meet the strict regulatory criteria. Likewise, the fact that the OPV regulations have been abolished is a factor than could be considered in determining whether Orimune was defective. *See* Restatement (Third) of Torts § 4 cmt. d (1998) ("When repeal or invalidation [of a statute or regulation] takes place post-injury, but prior to adjudication, the court may take the repeal or invalidation into account in deciding whether noncompliance with the statute or regulation renders the product defective.")

to establish a causal connection between a particular individual's contraction of polio, on the one hand, and the marginal difference in neurovirulence between vaccine derived from a seed compliant with the OPV regulations and vaccine developed from a non-compliant seed, on the other.[7]

On the surface this holding might appear to contradict the statement I made in *Sabin III* that "it must be concluded that by releasing vaccine lots whose monkey neurovirulence test results exceeded the regulatory criteria, DBS increased the risk of harm to persons who were vaccinated and . . . exposed to the shed virus." 774 F.Supp. at 955. However, in *Sabin III* I was not considering the issue of whether a dose of Orimune had been a proximate cause of a particular individual's paralysis: an inquiry which, under products liability law, requires proof of a causative connection between the paralysis and a defect in Orimune. Rather, I was addressing the question of whether by approving seeds not compliant with the OPV regulations, the United States had breached its duty to the members of the public, which it had assumed by virtue of its undertaking to regulate a potentially hazardous condition for the benefit of others. Resolution of that question required me to determine whether the United States had "increase[d] the risk of . . . harm" to those who were vaccinated or otherwise exposed to the live polio virus within the meaning of

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[7] If the vaccine lot from which the Orimune administered to Callahan itself passed the criteria set by the OPV regulations, a matter the parties appear to dispute, that would pose an additional obstacle to SLU's proof in this case. Although, as noted previously in the text and explained in *Sabin III,* 774 F.Supp. at 958, this fact is not relevant to the proximate cause analysis in a case against the United States, it might be fatal to a claim against Cyanamid, even if the claim were otherwise viable.

§ 24A of the Restatement (Second) of Torts.[8] In making that determination, I found that the neurovirulence criteria of the OPV regulations—which the government itself had adopted—provided "the best available scientific standard" for determining potential excessive neurovirulence and that the government had therefore increased the risk of harm to the public. *Id.*

I did not find, however, that Orimune was, in fact, excessively neurovirulent when administered to humans or that an OPV meeting the regulatory criteria would not have equally caused the *Sabin III* plaintiffs to contract polio. Once I found that the United States had breached its duty by increasing the risk of harm to the public, the only proximate causal connection I found necessary to make was the one established by the essential fact that if seed 45 B 85 (and seed 45 B 165) had not been improperly approved, the vaccine to which the *Sabin III* plaintiffs were exposed would never have been put into use. *Id.* at 958.

Several final comments, somewhat reiterative though they are, perhaps are in order to explain why I am holding the United States, but not Cyanamid, liable for contribution. Whether or not an oral polio vaccine that complied with the OPV regulations would have caused

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[8] The *Campagna* court, in quoting the language in question, recognized that I was not analyzing the element of proximate cause but was rather "[c]ommenting on an issue closely akin" to it. 767 A.2d at 1003. The accuracy of this reading is confirmed by the fact that the quoted language appears in the section of my opinion entitled "Existence of Duty," not the section entitled "Proximate Cause." Moreover, I prefaced my statement with the observation (based upon the evidentiary record) that "there is no necessary or definitive correlation between the results of monkey neurovirulence tests and a vaccine's neurovirulence when administered to humans. . . ." 774 F.Supp. at 955.

Callahan and the plaintiffs in the other *Sabin* cases to contract polio ultimately is unknowable and unprovable. What is known, or at least that which I found to be demonstrated by the record in the MDL cases, is that the OPV program "has resulted in the virtual eradication of wild poliovirus in the Western Hemisphere," that it was "perhaps the most successful public health program in history," and that the OPV manufactured by Lederle "has always been 'state of the art.' " *Sabin II,* 763 F.Supp. at 813. This combination of the unknowable and the known make it impossible for SLU to prevail on a claim against Cyanamid since, as I have indicated, such a claim, arising solely under products liability law, requires proof that a product defect caused the plaintiff to suffer injury.

The claim against the United States, however, turns on a more fundamental principle: the necessity of upholding the rule of law. In *Sabin II* I found that although the officials responsible for the establishment and implementation of the OPV program were "extraordinarily able professionals who consistently acted in the public interest as they reasonably perceived it to be," 763 F.Supp. at 813, I also found in *Sabin III* that they "arrogated to themselves the power to define what constituted an acceptable [public health] risk." 774 F.Supp. at 957. They purposely decided not to amend the regulations embodying the neurovirulence criteria they originally deemed proper because they believed that considerations of health policy so required. I have never questioned the subjective good faith of those officials or, indeed, the objective reasonableness of their decision from a public health perspective. But in taking the actions they did, they increased the risk that several more individuals would contract polio as a result of exposure to OPV than would have done so if the OPV regulations had been strictly followed. It may well be that the rest of us were

beneficiaries of a resultant harm suffered by a few. For that very reason, it is proper that we collectively be held liable for our government's actions.

A separate order effecting the rulings in this memorandum is attached.

ORDER

For the reasons stated in the accompanying memorandum, it is, this 25th day of January 2002, ORDERED that:

1. Plaintiff's Motion for Partial Summary Judgment in *St. Louis University v. United States* is granted.

2. Plaintiff's Motion for Summary Judgment in *American Cyanamid Co. v. St. Louis University* is granted.

Supreme Court, U.S.
FILED
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No. 03-557

IN THE

Supreme Court of the United States

ST. LOUIS UNIVERSITY,
Petitioner,

v.

AMERICAN CYANAMID COMPANY,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether in this products liability case arising under the court's diversity jurisdiction, the court of appeals properly affirmed the grant of summary judgment in the defendant's favor where the plaintiff—whose sole theory of liability was that the product failed to comply with since-revoked FDA regulations—failed to adduce any evidence of proximate causation sufficient to prove under Missouri tort law that the alleged regulatory violations in fact affected the safety of the product.

PARTIES TO THE PROCEEDING

The only parties to the proceeding are those identified in the petition for writ of certiorari.

RULE 29.6 STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Wyeth is the only publicly held company that owns 10% or more of American Cyanamid Company's stock. Wyeth is the parent corporation of American Cyanamid Company.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

PARTIES TO THE PROCEEDING ii

RULE 29.6 STATEMENT ii

TABLE OF AUTHORITIES iv

OPINIONS BELOW 1

JURISDICTION 1

STATEMENT OF THE CASE 1

The FDA's Former Oral Polio Vaccine Regulations 3

Proceedings Below 4

REASONS FOR DENYING THE PETITION FOR A WRIT OF CERTIORARI 6

ARGUMENT 7

I. THE COURT OF APPEALS' DECISION TURNED ENTIRELY ON THE APPLICATION OF MISSOURI TORT LAW AND IS NOT WORTHY OF REVIEW BY THIS COURT 7

II. THE COURT OF APPEALS' DECISION DOES NOT CONFLICT WITH THIS COURT'S OR ANY OTHER CIRCUIT'S DECISIONS, INCLUDING THE FOURTH CIRCUIT'S 9

III. SLU'S PLEA FOR THIS COURT TO OVERSEE FDA'S REGULATORY FUNCTION IS NOT A VIABLE BASIS FOR GRANTING THE PETITION 11

CONCLUSION 12

TABLE OF AUTHORITIES

CASES

Page(s)

Baker v. *United States*, 817 F.2d 560 (9th Cir. 1987) 10
Bauman v. *Conrad*, 342 S.W.2d 284 (Mo. Ct. App. 1961) 7, 8
Berkovitz v. *United States*, 486 U.S. 531 (1988) 9
Bluedorn v. *Missouri Pacific Railway Co.*, 25 S.W. 943 (Mo. 1894) 8
Brockett v. *Spokane Arcades, Inc.*, 472 U.S. 491 (1985) 7
Callahan v. *Cardinal Glennon Hospital*, 863 S.W.2d 852 (Mo. 1993) 2
Cort v. *Ash*, 422 U.S. 66 (1975) 7
Friend v. *Yokohama Tire Corp.*, 904 S.W.2d 575 (Mo. Ct. App. 1995) 9
In re Sabin Oral Polio Vaccine Products Liability Litigation, 984 F.2d 124 (4th Cir. 1993) 10
Loge v. *United States*, 662 F.2d 1268 (8th Cir. 1981) 10
Nesselrode v. *Executive Beechcraft, Inc.*, 707 S.W.2d 371 (Mo. 1986) 8
Wisniewski v. *United States*, 353 U.S. 901 (1957) 10

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The decision of the court of appeals (Pet. App. 1a-8a) is reported at 336 F.3d 307 (4th Cir. 2003). The decision of the district court (Pet. App. 34a-50a) is reported at 182 F. Supp. 2d 494 (D. Md. 2002).

JURISDICTION

The judgment of the court of appeals was entered on July 16, 2003. Pet App. 1a. The petition for a writ of certiorari was filed on October 10, 2003. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATEMENT OF THE CASE

For more than nine years, St. Louis University ("SLU") has pursued American Cyanamid Company ("American Cyanamid") and several other parties, including the United States, to recover roughly $16 million that SLU paid to sat-

isfy a medical malpractice verdict entered against it by a Missouri state court in 1991. In that case, a jury held SLU liable because its doctors had improperly treated an infection in an infant, Danny Callahan, thus compromising the child's immune system in a way that allowed the live poliovirus contained in his recently administered polio vaccine ("Orimune®") permanently to damage his central nervous system and paralyze him. The Missouri Supreme Court affirmed the verdict against SLU in 1993, holding that the evidence supported the jury's findings both with respect to SLU's negligence and the causal connection between that negligence and the child's injury. *See Callahan* v. *Cardinal Glennon Hosp.*, 863 S.W.2d 852 (Mo. 1993) (en banc).

After SLU paid the judgment in the state court case, it filed state and federal court actions seeking contribution against the federal government and American Cyanamid, respectively.[1] After some procedural wrangling, American Cyanamid brought a declaratory judgment action in the United States District Court for the District of Maryland (where SLU's case against the United States was pending) based on diversity jurisdiction. American Cyanamid sought a declaration that it had no liability to SLU. In response, SLU filed a counterclaim seeking contribution from American Cyanamid under Missouri law.

SLU's claims and counterclaims for contribution against American Cyanamid and the United States were premised on the same contention—that the Orimune administered to Danny Callahan in November 1978 violated the FDA's then-applicable regulations governing the manufacture, testing, and release of oral polio vaccine and that those alleged regulatory violations (if proven) would be sufficient, in and of themselves, to entitle SLU to recover some or all of the $16 million that it had earlier paid to Danny Callahan. SLU re-

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[1] SLU's case against the United States under the Federal Tort Claims Act is the subject of a separate petition for a writ of certiorari filed by SLU. *See St. Louis University* v. *United States*, No. 03-599 (filed Oct. 17, 2003).

lied mainly on the FDA's former regulations governing the "neurovirulence" of the vaccine when tested in monkeys, claiming that various lots of Orimune were made and tested by American Cyanamid and released for use by the FDA in violation thereof. Pet. 3, 4. SLU's legal position was that these regulatory violations were necessarily the proximate cause of Danny Callahan's injury because, had the vaccine not been released, the child would not have received it. *See* Pet. 4 ("[H]ad the regulations been followed, the only vaccine available to Danny would have been the inactive Salk vaccine, which presents *no polio* risk."); Pet. 9-10 ("[H]ad Cyanamid actually complied with the regulations, Orimune would never have reached Danny's lips.... Danny would have been inoculated with an alternative vaccine: the Salk Vaccine.").

The FDA's Former Oral Polio Vaccine Regulations

Oral poliovirus vaccine consists of live, but weakened, strains of poliovirus that stimulate immunity in the recipient by invoking a mild infection. The vaccines were routinely subject to a barrage of tests imposed by FDA regulations that were promulgated in the early 1960s. One such regulation, in effect when Danny Callahan's vaccine was made, required that each batch (or "monopool") of vaccine be tested by injecting a sample into monkeys and then microscopically evaluating their central nervous system tissues for lesions. *See* C.A. App. 103-104. Under the regulations, different dilutions of each monopool were injected into two groups of monkeys. One group was injected intrathalamically (in the thalamus, which is located in the brain), and the second group was injected intraspinally (in the lumbar region of the spine). *See id.* After a period of observation, the monkeys were sacrificed, and a highly trained pathologist conducted a microscopic examination of the tissue taken from the monkeys' brains and spinal cords. *See id.* at 104. The pathologist evaluated the tissue samples for evidence of damage caused by the weakened poliovirus and, pursuant to procedures established by the FDA, assigned a numerical score from 0 to 4 to each sample.

Under the regulations, an identical test was performed on monkeys injected with a "Reference Attenuated Poliovirus," a poliovirus that the FDA chose as a control. *See* C.A. App. 104. The results on each monopool were then compared with the results seen historically on the Reference. Under the regulations, "[t]he virus pool under test is satisfactory for poliovirus vaccine only if . . . a comparative analysis of the test results demonstrate[s] that the neurovirulence of the test virus pool does not exceed that of the Reference Attenuated Poliovirus." *Id.*

In 1991, the FDA amended these regulations and substantially changed the way that monkey neurovirulence tests were to be conducted and evaluated. *See* C.A. App. 111. The FDA made those changes based upon its conclusion, after decades of experience with oral polio vaccine, that there was no correlation between the very small differences in monkey neurovirulence test scores in monopools that had been released and the risk of paralysis in humans:

> No single vaccine lot has been associated with an increased incidence of poliomyelitis. The lots that have been identified as associated with a case of paralytic poliomyelitis have had typically low scores when tested by FDA and the manufacturer for neurovirulence in monkeys.

Id. at 113. The FDA also concluded that "all vaccine previously released or distributed is deemed to meet the requirements of these amended regulations." *Id.* at 116. Then, in 1996, the FDA revoked all of its oral polio vaccine regulations on the express ground that they were "obsolete or no longer necessary to achieve public health goals." *Id.* at 133.

Proceedings Below

On American Cyanamid's motion for summary judgment, the district court held that even assuming the now-revoked FDA regulations set the standard of conduct under state tort law and that a violation had in fact taken place—

SLU failed to present any evidence to establish proximate causation under Missouri law.[2] Pet. App. 44a-47a. The district court explained that, as a matter of Missouri law, SLU could not prevail against American Cyanamid without expert testimony that the alleged violation of the FDA's monkey neurovirulence regulations increased the risk to humans of vaccine-associated paralysis, and that either Danny Callahan's paralysis or its severity resulted from the increased risk allegedly created by that regulatory violation. *Id.* at 45a-47a. Because SLU had failed to submit any evidence in this regard, much less expert testimony, the trial court granted American Cyanamid's summary judgment motion. *Id.* at 46a-47a ("[A]s the absence of any proffered expert testimony by SLU affirms, the results of th[e] [monkey neurovirulence] tests alone are not sufficient to establish a causal connection between a particular individual's contraction of polio, on the one hand, and the marginal difference in neurovirulence between vaccine derived from a seed compliant with the [oral polio vaccine] regulations and vaccine developed from a non-compliant seed, on the other.").[3]

The Fourth Circuit affirmed the grant of summary judgment in favor of American Cyanamid in all respects, holding that "SLU has simply failed to present any competent evidence showing that the defect in the vaccine—excessive neurovirulence—proximately caused Danny's injuries." Pet. App. 5a. The court of appeals explained that even in cases where the violation of a statute or regulation amounts to negligence *per se*, "Missouri law is unambiguous in its requirement that the plaintiff must still prove that the violation proximately caused his injuries." *Id.* at 6a. Thus, because "SLU presented no expert testimony showing that Danny Callahan would not have contracted polio or would have contracted a less severe case of polio had he been given

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[2] It is undisputed that Missouri law applies to this case. *See* Pet. App. 4a, 39a.

[3] In the same opinion, however, the district court held the United States liable in contribution to SLU. Pet. App. 39a-44a.

a vaccine complying with the neurovirulence regulations," summary judgment in favor of American Cyanamid was warranted. *Id.*[4]

In a separate opinion, the court of appeals also reversed the grant of summary judgment against the United States and directed that judgment be entered in the government's favor, holding that, just as the manufacturer of the polio vaccine could not be liable without proof that an alleged regulatory violation actually resulted in a vaccine that was more likely to cause paralysis, neither could the United States be held liable. Pet. App. 18a-27a.

SLU did not seek rehearing or rehearing *en banc* of the summary judgment in favor of American Cyanamid, but it did seek rehearing *en banc* of the decision in favor of the United States. On August 12, 2003, the court of appeals denied SLU's petition, stating that no judge on the court had voted in favor of further review. No. 03-599 Pet. App. 44a.

REASONS FOR DENYING THE PETITION FOR A WRIT OF CERTIORARI

This case is decidedly not worthy of review by this Court. It is a routine products liability case involving the application of garden-variety rules of state tort law. The case is in federal court only because of the parties' diversity of citizenship. There are no substantial questions of federal law (indeed, the FDA regulations at issue were revoked years ago) and no conflicts among the circuits that need to be resolved. The Court should deny the petition.

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[4] In a concurring opinion, Judge Luttig "join[ed] the judgment of the court in this case for the straightforward reason that SLU failed to proffer evidence of proximate causation sufficient to satisfy the Missouri tort standards." Pet. App. 7a. Judge Luttig observed that "SLU proffered no evidence that the vaccine, had it been defect-free, would not have caused Danny Callahan's injuries. As such, SLU failed to create a genuine issue as to that central proximate cause question, without which it cannot survive [American Cyanamid's] summary judgment motion." Pet. App. 7a-8a.

ARGUMENT

I. THE COURT OF APPEALS' DECISION TURNED ENTIRELY ON THE APPLICATION OF MISSOURI TORT LAW AND IS NOT WORTHY OF REVIEW BY THIS COURT.

This diversity case involves only the application of straightforward principles of Missouri products liability law and is thus not worthy of further review by this Court. Indeed, questions of state law are rarely, if ever, reviewed by the Court absent a plain error by the court of appeals. *See Brockett* v. *Spokane Arcades, Inc.*, 472 U.S. 491, 500 & n.9 (1985) (Court "will defer to lower courts on state-law issues unless there is a 'plain' error . . . [or] the lower court is 'clearly wrong' " (internal citations omitted)); *Cort* v. *Ash*, 422 U.S. 66, 73 n.6 (1975) ("[T]his Court must necessarily depend upon the district courts and courts of appeals for initial determinations of questions of state law; indeed, our practice of deference to such determinations should generally render unnecessary review of their decisions in this respect.").

Here, the decision in favor of American Cyanamid by the court of appeals was manifestly correct under Missouri tort law. Missouri law explicitly requires a plaintiff to prove more than the mere existence of a regulatory or statutory violation before liability will be imposed. A regulatory violation would, at most, establish a breach of duty, but it would not suffice to satisfy the separate element of proximate causation.[5] *See Bauman* v. *Conrad*, 342 S.W.2d 284, 287 (Mo. Ct. App. 1961). SLU was still required to come forward with admissible evidence, in the form of expert testimony, that the alleged regulatory violation increased the risk of vac-

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[5] Contrary to SLU's assertion, the district court never made any "factual findings" that American Cyanamid violated the monkey neurovirulence regulations. Pet. 8. The district court, in fact, explained that it "did not find . . . that Orimune was . . . excessively neurovirulent when administered to humans" (Pet. App. 48a) and observed that "[i]f the vaccine lot from which the Orimune administered to [Danny] Callahan itself passed the criteria set by the [oral polio vaccine] regulations, a matter the parties appear to dispute, that would pose an additional obstacle to SLU's proof in this case" (*id.* at 47a n.7).

cine-associated paralysis such that a jury could find that Danny Callahan either would not have become paralyzed at all or would have been paralyzed less severely had he received a vaccine that complied with the then-existing regulations. Pet. App. 5a-6a. The court of appeals held that SLU had no such proof: "SLU presented no expert testimony showing that Danny Callahan would not have contracted polio or would have contracted a less severe form of polio had he been given a vaccine complying with the neurovirulence regulations."[6] *Id.* at 6a. This is exactly what Missouri law requires. *See Nesselrode* v. *Executive Beechcraft, Inc.*, 707 S.W.2d 371, 375-376 (Mo. 1986) (*en banc*) (plaintiff in manufacturing defect case must prove that the defect caused his injuries by proving that had the product been defect-free the injury would not have occurred).

The court of appeals also rejected under Missouri law SLU's argument that the FDA's regulations somehow created a "presumption" that "any vaccine exceeding" the former regulatory standard "posed an unacceptable risk that the recipient would contract polio." Pet. App. 26a. "[S]uch an approach," the court held, "is utterly inconsistent with Missouri law," because it would create automatic liability once a plaintiff has demonstrated a regulatory violation. *Id.* at 27a (citing Missouri cases). The court was, of course, exactly right. As the intermediate court of appeals in Missouri held long ago, "[t]he mere fact that an ordinance has been violated is not sufficient basis for an inference that such violation was the proximate cause of plaintiff's injuries." *Bauman*, 342 S.W.2d at 287. A violation (involving the posted speed limit in that case) "raises *no presumption* that the accident causing the injury was caused by excessive speed." *Id.* at 288 (emphasis added); *see also Bluedorn* v. *Missouri Pac. Ry. Co.*, 25 S.W. 943, 946-947 (Mo. 1894) (*en*

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[6] In the same vein, the court of appeals held that "none of SLU's experts testified that increased [monkey] neurovirulence led to increased incidence of vaccine-associated polio, nor were any qualified to render such an opinion." Pet. App. 5a n.3.

banc) ("[R]ecovery cannot be had upon mere proof of injury and defendant's breach of a statute or ordinance. The plaintiff must prove that the breach of regulation was the proximate cause of his injury."); *Friend* v. *Yokohama Tire Corp.*, 904 S.W.2d 575, 579 (Mo. Ct. App. 1995) ("One of the elements of a negligence per se action is that the violation of the statute was the proximate cause of the injury.")

Any reading of the court of appeals' decision makes clear that the outcome turned solely on Missouri state law; this case thus raises no important questions of federal law, particularly given that the FDA regulations at issue—the only arguably "federal" aspect of this case—are no longer in effect. This case thus should be treated no differently than the ordinary products liability case where final review routinely takes place not in this Court, but in the court of appeals.

II. THE COURT OF APPEALS' DECISION DOES NOT CONFLICT WITH THIS COURT'S OR ANY OTHER CIRCUIT'S DECISIONS, INCLUDING THE FOURTH CIRCUIT'S.

Contrary to SLU's argument, this case presents no deviation from the "binding precedent" in *Berkovitz* v. *United States*, 486 U.S. 531 (1988) (Pet. 12), and it does not conflict in any way with the decisions of any other court of appeals (*id.* at 12-13). The cases upon which SLU relies—*Berkovitz*, *Loge*, and *Baker*—are all inapplicable to the factual and legal issues presented here.

In *Berkovitz*, this Court granted certiorari "to resolve a conflict in the Circuits regarding the effect of the *discretionary function exception* on claims arising from the Government's regulation of polio vaccines." *Berkovitz*, 486 U.S. at 534-535 (emphasis added). The Court never reached the issues of liability (or, more specifically, causation) under state law; indeed, those issues were not even presented. The Court held only that the plaintiffs' claim that the government approved the release of a non-compliant vaccine lot "survives the Government's motion to dismiss" and thus remanded the case for further proceedings. *See id.* at 547-548.

Likewise, the courts of appeals in *Baker* v. *United States*, 817 F.2d 560 (9th Cir. 1987), and *Loge* v. *United States*, 662 F.2d 1268 (8th Cir. 1981), also dealt with the discretionary function exception to the Federal Tort Claims Act; neither reached issues of causation or liability. *Baker*, 817 F.2d at 566 ("Our holding that the plaintiffs' claims are not barred by [the discretionary function exception] does not end the inquiry into whether the Bakers have established a cause of action. Whether the Bakers have a claim against the government depends on whether a private person under like circumstances could be found liable in tort under applicable state law." (footnote omitted)); *Loge*, 662 F.2d at 1275 (reversing grant of motion to dismiss and remanding case for further proceedings).

And contrary to SLU's argument, the court of appeals' opinion in this case certainly does not "flout[] the fundamental doctrine of *stare decisis* by rejecting the binding Fourth Circuit precedent" of *In re Sabin Oral Polio Vaccine Products Liability Litigation*, 984 F.2d 124 (4th Cir. 1993). Pet. 15. Indeed, there is no conflict. The court of appeals' decision in *In re Sabin* dealt solely with claims against the United States and was governed by Florida and Maryland law, not Missouri law. Pet. App. 22a-23a. Whatever the rules of decision may require in Florida and Maryland, Missouri law clearly mandates that proximate cause in a case against a product manufacturer must be established through admissible expert testimony where the issues are, as here, based on science that is unfamiliar to the layperson. *See id.* at 6a, 7a, 25a-26a. Moreover, an intra-circuit conflict ordinarily is not a sufficient basis for granting a writ of certiorari. *See Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957) (*per curiam*) ("It is primarily the task of a Court of Appeals to reconcile its internal difficulties."). This is particularly true where the court of appeals, as it did here, expressly addressed the supposed conflict and had no difficulty distinguishing the authority on which SLU relies. Pet. App. 22a-27a.

III. SLU'S PLEA FOR THIS COURT TO OVERSEE FDA'S REGULATORY FUNCTION IS NOT A VIABLE BASIS FOR GRANTING THE PETITION.

SLU's argument that certiorari in this case "would restore uniformity to the federal vaccine regulations and uphold public confidence in the regulatory system" (Pet. 13) not only fails to provide a viable basis for review by this Court, but it is also frivolous. The FDA expressly changed its regulations in 1991 to preclude the overly technical interpretation advanced by SLU's experts (an interpretation, incidentally, never accepted by the FDA). There was no dispute in the court below, and SLU offered no expert to testify, that any of the vaccine that Danny Callahan received did not completely satisfy all regulatory requirements in place in 1991 and thereafter. Indeed, it was undisputed that the FDA made those changes in 1991 based on its scientific conclusion that the small differences in monkey neurovirulence scores had no correlation to the safety of oral polio vaccine in humans.

Moreover, all of the oral polio vaccine regulations were revoked by the FDA in 1996 on the express ground that they were "obsolete or no longer necessary to achieve public health goals." C.A. App. 133. Further review of this case will do nothing to promote the federal regulatory process or the public's confidence in that process where the process is no longer governed by regulatory standards.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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